

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE SUBOXONE (BUPRENORPHINE
HYDROCHLORIDE AND NALOXONE)
ANTITRUST LITIGATION**

THIS DOCUMENT RELATES TO:,

Wisconsin, et al. v. Indivior Inc. et al.
Case No. 16-cv-5073

**STATE OF WISCONSIN
By Attorney General Brad D. Schimel, et al.**

Plaintiffs,

v.

**INDIVIOR INC. f/k/a RECKITT BENCKISER
PHARMACEUTICALS, INC., et al.**

Defendants.

**MDL NO. 2445
13-MD-2445**

CIV. A. NO. 16-5073

Goldberg, J.

November 24, 2020

MEMORANDUM

Defendant Reckitt Benckiser, Inc. (“Defendant”) manufactures Suboxone, a drug commonly used to combat opioid addiction.¹ Suboxone previously came in tablet form, but in 2010, citing safety concerns, Defendant effectuated a change in the administration of this drug, switching from tablet to sublingual film. Various purchasers/consumers of Suboxone claimed that this switch was anticompetitive and solely designed to maintain Defendant’s market exclusivity—a scheme known as a “product hop.” These claims have resulted in multi-district, antitrust litigation before this Court.

¹ Reckitt is currently known as Indivior, Inc. In December 2014, Reckitt Benckiser Pharmaceuticals, Inc. was demerged from its prior parent, the Reckitt Benckiser Group PLC, into Indivior PLC. Although Indivior is technically the named defendant in this case, the pleadings and many of the relevant exhibits use the name “Reckitt.”

As discovery and class certification litigation have come to a close, the parties have raised numerous challenges under Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993), seeking exclusion of all or selected portions of nine expert witnesses anticipated opinions. This Opinion explains my reasoning for the resolution of these motions and will hopefully set forth a clearer path towards trial.

I. FACTUAL AND PROCEDURAL BACKGROUND²

The Plaintiffs in this multi-district litigation case allege anticompetitive conduct by Defendant Reckitt Benckiser, Inc. in connection with their Suboxone product. Plaintiffs' claims focus on a relatively new theory of antitrust liability, referred to as a "product hop," pursuant to the unique regulatory and statutory scheme that governs the marketing and distribution of pharmaceutical drugs. Under this theory, a pharmaceutical company makes modest reformulations to a brand-name drug prior to the expiration of its market exclusivity for the purpose of stymieing generic competition and preserving monopoly profits.

The Plaintiffs are comprised of a class of Direct Purchasers of Suboxone ("Direct Purchasers" or "DPPs"), a class of End Payors of Suboxone ("End Payors" or "EPPs"), and a group of States' Attorneys General (the "States") (collectively, "Plaintiffs"). These Plaintiffs claim that Defendant switched from a Suboxone tablet to a sublingual Suboxone film for the purpose of foreclosing generic competition. According to Plaintiffs, this switch (the "product hop") was accompanied by Defendant disparaging the tablet through fabricated safety concerns and ultimately removing Suboxone tablets from the market just as generic Suboxone tablets were able to begin

² Rather than re-hashing the complicated regulatory background and factual basis of this case, I incorporate by reference the history set forth in my prior decision certifying a class for both the DPPs and EPPs. In re Suboxone, 421 F. Supp. 3d 12 (E.D. Pa. 2019), aff'd, 967 F.3d 264 (3d Cir. 2020). To the extent necessary, I will discuss facts that are pertinent to each particular expert at issue.

competing. Defendant is also accused of having manipulated FDA regulations to delay the entry of generic Suboxone onto the market through the filing of an unsubstantiated Citizen Petition and of “misconduct” during the shared Risk Evaluation and Mitigation Strategies (“REMS”) process. According to Plaintiffs, Defendant’s conduct foreclosed competition, thereby allowing Defendant to unlawfully maintain a monopoly in violation of Section 2 of the Sherman Act and overcharge for its Suboxone products. Defendant readily acknowledges the product switch, but strenuously responds that the switch was done for the pro-competitive purpose of marketing and selling an improved, safer, and superior product.

During the pendency of Defendant’s appeal of the class certification ruling to the Third Circuit, I directed the parties to file any Daubert motions that would not be impacted by the Third Circuit’s certification decision. The parties have filed the following motions: (1) the DPPs’ Motion to Exclude Certain Opinions of Defendant’s Experts Nicholas M. Fleischer and Sheldon T. Bradshaw; (2) the States’ Motion to Exclude the Testimony of Defendant’s Expert Dolores Curtis, Ph.D.; (3) Defendant’s Omnibus Motion to Exclude Certain of the Opinions of Nicholas Jewell, Laurence Westreich, Yvonne Tso, Robert Verscharen, Patricia Zettler, and Deborah Jaskot; and (4) Defendant’s Motion to Exclude Plaintiffs’ Expert Opinions Asserting or Relying upon Assertions that Alleged Reckitt Safety Messages Were “False,” “Misleading,” “Disparaging,” “Fabricated,” “Fraudulent,” “Sham,” or “Deceptive.”

II. STANDARD OF REVIEW

Federal Rule of Evidence 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) The expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) The testimony is based on sufficient facts or data;

- (c) The testimony is the product of reliable principles and methods;
and
- (d) The expert has reliably applied the principles and methods to the facts of the case

Fed. R. Evid. 702. Rule 702 places district courts in the role of “gatekeeper,” requiring courts to “ensure that any and all [expert] testimony . . . is not only relevant, but reliable.” Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147 (1999) (quoting Daubert, 509 U.S. at 589). The party offering an expert must demonstrate, by a preponderance of the evidence, that the expert’s qualifications and opinions comply with Federal Rule of Evidence 702. See Daubert, 509 U.S. at 592–93 (citation omitted). Rule 702 has “a liberal policy of admissibility,” Pineda v. Ford Motor Co., 520 F.3d 237, 243 (3d Cir. 2008) (quotation omitted), and “the rejection of expert testimony is the exception rather than the rule.” Fed. R. Evid. 702, Advisory Comm Notes (2000). As the Court in Daubert stated: “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” 509 U.S. at 595.

The Daubert inquiry “embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit.” Schneider ex re. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (citations omitted).

A. Qualification

In Waldorf v. Shuta, 142 F.3d 601 (3d Cir. 1998), the United States Court of Appeals for the Third Circuit articulated the “qualification” standard for an expert:

Rule 702 requires the witness to have “specialized knowledge” regarding the area of testimony. The basis of this specialized knowledge “can be practical experience as well as academic training and credentials.” . . . We have interpreted the specialized knowledge requirement liberally, and have stated that this policy of liberal admissibility of expert testimony “extends to the substantive as well as the formal qualification of experts.” . . . However, “at a minimum,

a proffered expert witness . . . must possess skill or knowledge greater than the average layman”

Id. at 625 (citations omitted).

Construing this standard, the Third Circuit has “eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more generalized qualifications.” In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741 (3d Cir. 1994). In other words, “an expert’s qualifications should be assessed ‘liberally,’ recognizing that ‘a broad range of knowledge, skills, and training qualify an expert as such.’” Thomas v. CMI Terex Corp., No. 07-3597, 2009 WL 3068242, at *5 (D.N.J. Sept. 21, 2009) (quoting Paoli, 35 F.3d at 741). An expert will not be excluded “simply because [the court] does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.” Holbrook v. Lykes, Bros. S.S. Co., 80 F.3d 777, 782 (3d Cir. 1996). The focus, instead, is on whether the qualifications that an expert does have provide a foundation for the witness to testify meaningfully on a given matter. See Buzzerd v. Flagship Carwash of Port St. Lucie, Inc., 669 F. Supp. 2d 514, 522 (M.D. Pa. 2009).

B. Reliability

The reliability restriction requires that the testimony be based upon “the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation’” and that the expert have “‘good grounds’ for his or her belief.” Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) (quotations omitted). In that respect, reliability mandates an examination into the expert’s conclusions in order to determine “whether [the conclusions] could reliably flow from the facts known to the expert and [the] methodology used.” In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prod. Liab. Litig., 706 F.3d 217, 225 n.7 (3d Cir.

2013) (quoting Oddi v. Ford Motor Co., 234 F.3d 136, 146 (3d Cir. 2000) (internal quotation marks omitted)).

The Third Circuit has identified the following non-exhaustive factors to be taken into consideration when evaluating the reliability of a particular methodology: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. Elcock v. Kmart Corp., 233 F.3d 734, 745–46 (3d Cir. 2000). Although this list of factors is lengthy, not each factor will be relevant to every reliability analysis. The “test of reliability is ‘flexible.’” Kumho, 526 U.S. at 141. According to the Supreme Court, “Daubert’s list of specific factors neither necessarily nor exclusively applies to all experts.” Id. The relevance of the Daubert factors depends “on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.” Id. at 150 (internal quotation marks and citations omitted).

Importantly, the rule does not require the party proffering the expert to demonstrate the “correctness” of the expert’s opinion. Paoli, 35 F.3d at 744 (concluding that the “evidentiary requirement of reliability” amounts to a lower burden “than the merits standard of correctness”). Rather, the party need only demonstrate “by a preponderance of the evidence” that the expert’s opinion bears adequate indicia of reliability. Id. Indeed, “[a] judge will often think that an expert has good grounds to hold the opinion . . . even though the judge thinks the opinion otherwise incorrect.” Id. Therefore, “[t]he focus . . . must be solely on principles and methodology, not on the conclusions that they generate.” Daubert, 509 U.S. at 595. “When the methodology is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of

relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility." i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 852 (Fed. Cir. 2010), aff'd, 564 U.S. 91 (2011).

C. Fit

The issue of fit "is one of relevance and expert evidence which does not relate to an issue in the case is not helpful." In re TMI Litig., 193 F.3d 613, 670 (3d Cir. 1999). The standard for fitness is "not that high" but is "higher than bare relevance." Paoli, 35 F.3d at 745. To determine whether an expert's testimony "fits" the proceedings, this Court asks whether it "will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a); see also UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres, 949 F.3d 825, 835 (3d Cir. 2020). "'Fit' is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." Id. (quoting Daubert, 509 U.S. at 591). "Thus, even if an expert's proposed testimony constitutes scientific knowledge, his or her testimony will be excluded if it is not scientific knowledge *for purposes of the case*." Id. (quoting Paoli, 35 F.3d at 743 (emphasis in original)).

III. THE DIRECT PURCHASER PLAINTIFFS' OMNIBUS *DAUBERT* MOTION

I first consider the DPPs' Daubert motion to preclude certain opinions by two of Defendant's experts, Nicholas Fleischer and Sheldon Bradshaw.

A. Opinions of Nicholas Fleischer

The DPPs' first challenge involves Dr. Nicholas Fleischer. In order to understand Dr. Fleischer's opinions, some context is necessary.

Plaintiffs’ antitrust case theorizes, in part, that, absent Defendant’s delay during the shared REMS process,³ generic tablet manufacturers Amneal and Actavis would have brought their generic product to market sooner. In support of that theory, the DPPs offer expert Deborah Jaskot, who concludes that there were no FDA regulatory obstacles to the approval of Amneal and Actavis’ ANDAs, and that Defendant’s conduct in the REMS process created the sole obstacle and delay in Amneal and Actavis’ ability to bring their generic product to market. In response, Dr. Fleischer opines on “regulatory issues involved with the review and approval of Amneal’s ANDA 203136 [and] Actavis ANDA 91422.” (Decl. of Dan Chiorean (“Chiorean Decl.”), Ex.1 (“Fleischer Rep.”) ¶ 2.) Dr. Fleischer’s opinions will also establish that both ANDAs had multiple deficiencies that delayed their approval.

The DPPs now seek to exclude Dr. Fleischer’s opinions on two subject areas, which I discuss separately.

1. Opinion Testimony Regarding FDA Form 483

One of the key issues in this case concerns whether Defendant’s conduct during the shared REMS process resulted in a delay in the approval of the Abbreviated New Drug Applications (“ANDA”s) for generic Suboxone. The DPPs’ regulatory expert, Deborah Jaskot, opined that if the generics’ REMS “were approved by FDA between August 22, 2012 and September 1, 2012, there were no other regulatory hurdles or obstacles that would have prevented final approval of these two ANDAs during that same time frame.” (Def.’s Opp’n DPPs’ Mot., Ex. 5, Report of Deborah Jaskot

³ As explained in the class certification decision, REMS is a Risk Evaluation and Mitigation Strategy to “manage known or potential serious risks associated with a drug product and is required by the FDA to ensure that the benefits of a drug outweigh its risks. <https://www.btodrems.com/SitePages/Welcome.aspx>. The FDA can also require that generic sponsors coordinate with the manufacturer of the branded counterpart drug for the purposes of creating a Single Shared REMS program (“SSRS”), which is a single REMS program to be used by both the sellers of the brand drug and AB-rated generic equivalents.

(“Jaskot Rep.”) ¶ 18.) Deborah Jaskot also noted that the FDA, in May 2012, had inspected the MacFarlan Smith facility—the source of Actavis’ active pharmaceutical ingredient—and did not find any compliance issues or issue any FDA Form 483s, which would have indicated Food, Drug and Cosmetic Act problems.⁴ (Def.’s Opp’n DPPs’ Mot., Ex. 6, Jaskot Rebuttal Rep. ¶ 62.)

In Dr. Fleischer’s responsive report, he concluded, based on an FDA internal progress log, that “Actavis’ compliance deficiencies were separate from the pending REMS issues and Actavis’ ANDA could not have been approved prior to their resolution on November 29, 2012.” (Fleischer Rep. ¶ 130.) To rebut Ms. Jaskot’s assertion about MacFarlan Smith facility, Dr. Fleischer reviewed the FDA’s records regarding the May 2012 inspection and discovered that the FDA had, in fact, issued an FDA Form 483. In paragraph four of Dr. Fleischer’s June 5, 2019 Supplemental Report, he stated that he “consulted with [his] Current Good Manufacturing Practice (“cGMP”) associates at The Weinberg Group [Nita U. Patel and John T. LoPiccolo] who provided [an analysis] of the observations [in Form FDA 483].” (Chiorean Decl., Ex. 3, Fleischer Suppl. To Sur-Rebuttal Report ¶ 4 & n.4.) According to that Report, Dr. Fleischer concluded that the Macfarlan Smith facility faced “a combination of unverified analytical validation, untrained analysts, with potential micro contaminant issue leading to potential safety risks” that could have caused a delay in the approval of Actavis’ ANDA. (*Id.* ¶ 4.) Dr. Fleischer opined that “Actavis’ compliance deficiencies [at that

⁴ “An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food, Drug and Cosmetic (FD&C) Act and related Acts. FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific and significant. Observations are made when in the investigator’s judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health.” [https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions#:~:text=A%3A%20An%20FDA%20Form%20483,FD%26C\)%20Act%20and%20related%20Acts](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions#:~:text=A%3A%20An%20FDA%20Form%20483,FD%26C)%20Act%20and%20related%20Acts).

facility] prevented the FDA from approving its ANDA prior to November 2012.” (Fleischer Sur-Rebuttal Rep. ¶ 24.)

The DPPs contend that this opinion is inadmissible under Daubert because Dr. Fleischer simply took the opinions of two individuals not designated as experts and put them into his own words to “make it flow better.” (Chiorean Decl., Ex. 7, Jan. 7, 2020 Dep. of Nicholas Fleischer (“Fleischer Jan. 7, 2020 Dep.”) 32:4–12; 121:21–122:13.) According to the DPPs, for each of the “observations” made about deficiencies at the Macfarlan Smith facility, Dr. Fleischer merely adopted the analysis provided to him by Mr. LoPiccolo and Dr. Patel and “transcribed it as the way to get the message across about the seriousness of the observation.” (Id. at 122:18–123:6.) The DPPs point out that Dr. Fleischer did not know what methodology Mr. LoPiccolo and Dr. Patel employed in reaching their opinions. (Id. at 34:19–22.) The DPPs further contend that neither Mr. LoPiccolo nor Dr. Patel submitted reports, and their opinions were rendered outside the discovery period, depriving the DPPs of the ability to test the veracity, reliability, education, experience, methodology, or process of these individuals.

The DPPs are correct that “an expert cannot simply be the mouthpiece of another expert.” St. Paul Fire & Marine Ins. Co. v. Nolen Grp., Inc., No. 02-8601, 2005 WL 1168380, at *10 (E.D. Pa. May 13, 2005); see also In re: James Wilson Assocs., 965 F.2d 160, 173 (7th Cir.1992) (“[T]he judge must make sure that the expert isn't being used as a vehicle for circumventing the rule against hearsay.”) Nonetheless, “[w]hile experts may not simply ‘parrot’ ideas of other experts,” they “are permitted to rely on materials used by other experts in developing their own opinions.” I.B.E.W. Local Union 380 Pension Fund v. Buck Consultants, No. 03-4932, 2008 WL 2265269, at *3 (E.D. Pa. June 3, 2008) (quotations omitted). Experts “may use a mix of objective data and subjective analysis from another expert to . . . create an admissible report,” and the testifying expert’s knowledge regarding the underlying facts “go[es] to the weight accorded to [that expert’s] report

and testimony, rather than its admissibility.” Id. (quoting In re Wagner, No. 06-1026, 2007 WL 966010, at *4 (E.D. Pa. Mar. 29, 2007)). Indeed, under Federal Rule of Evidence 703, “an expert may rely on any facts or data ‘of a type reasonably relied upon by experts in the particular field in forming opinions,’” even if those underlying facts or data are themselves inadmissible. St. Paul Fire & Marine, 2005 WL 1168380, at *9 (quoting Fed. R. Evid. 703). “Cases have recognized that an expert may rely on the work of others, but the expert must be able to testify to the veracity of that work.” Id.; see also Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd., 286 F.R.D. 266, 271 (W.D. Pa. 2012) (“[I]t is well settled that one expert may rely upon another expert’s opinion in formulating his own.”).

In light of the above precedent, and after review of the pertinent expert reports, I conclude that Dr. Fleischer’s opinions—which are based in part on information received from others—are admissible. I disagree with the DPPs that Dr. Fleischer acted as a “mouthpiece” for his colleagues’ opinions. Dr. Fleischer was presented with Ms. Jaskot’s rebuttal report and was asked to provide responses to specific issues outlined in that report. (Fleischer Jan. 7, 2020 Dep. 20:1–14.) Dr. Fleischer was also asked to review the FDA Form 483 that showed problems during the inspection of the Macfarlan Smith facility. (Id. at 21:10–16.) Repeatedly, he testified that he made his own observations and formed his own opinions about what that FDA Form 482 demonstrated, and turned to his colleagues solely for consultation and confirmation of opinions he independently formed:

- “I consulted with [Patel and LoPiccolo] only from the purpose of asking them to confirm my observations and my opinions about my review of the 482, to see if they would concur that my opinions and evaluations was similar to what they would have opined in seeing the 483.” (Id. at 23:2–8.)
- “When I received that 483 and reviewed it, I found it to be a serious list of observations. And I sent the 483 to Dr. Patel and Mr. LoPiccolo and said—basically, I told them, I said, I think these are serious, but I would like your confirmation as to if you concur with my opinion that these are serious observations.” (Id. at 25:13–20.)

- “I read the 483. I had an opinion that these were serious-enough findings that could impact the FDA making a determination whether a facility was in compliance or not. And that is why I went to Dr. Patel and Mr. LoPiccolo, to confirm my observations that they would agree that they were of a serious nature.” (Id. at 28:13–21.)
- “As I said, I’m not repeating, I’m taking [Patel and LoPiccolo’s] opinions and editing them into my words. . . . [The Supplemental Sur-Rebuttal Report is] not a conduit of [Patel’s and LoPiccolo’s] opinions. It is a—taking their opinions and putting them into the words that I wanted to state based on my analysis of those observations.” (Id. at 32:1–12.)
- “I did not supervise [Patel and LoPiccolo]. I just sent them the 483 and asked them basically, what I’ve been saying all along, ‘do you concur with my opinion that these are serious observations.’ . . . [T]heir main responsibility at the Weinberg Group is dealing with GMP-type issues, almost on a day-to-day basis, which I don’t do on a day-to-day basis. So for that reason I said, you know, in order to confirm my opinion, I should ask them to see if they draw the same conclusions as I did.” (Id. at 33:2–17.)
- “I did not even mention to [Patel and LoPiccolo] what the case was or what drugs they were. I just asked them—as I stated several times before, I had said, ‘do you interpret these observations the same way I do that these are serious observations,’ without specificity as to what drugs were involved.” (Id. 45:1–8.)

Dr. Fleischer’s reliance on his colleagues to confirm his already-formulated conclusion does not constitute a basis for exclusion. “[A]n expert may expand his or her knowledge by consulting colleagues and journal articles. To hold otherwise would be to require scientists to develop all of their knowledge through their own clinical work or experiments. This is an unrealistic expectation and it ignores the reality of science as a collaborative process.” Adel v. Greensprings of Vermont, Inc., 363 F. Supp. 2d 683, 692 (D. Vt. 2005). “It would be strange, indeed, if the mere fact that an expert consulted with a similarly qualified colleague to test her theories rendered her conclusions *less* reliable. That [the expert] does not have a record of the exact changes [her colleague] proposed (and which were adopted) does not make her method unreliable, although it is

a perfectly legitimate ground for cross-examination.” Wolfe v. McNeil-PPC, Inc., No. 07-348, 2011 WL 1673805, at *6 (E.D. Pa. May 4, 2011).

The record also reflects that Dr. Fleischer meets the liberal standard for qualification to render these opinions. He testified that cGMPs are “something that [he] encounter[s] in [his] work in helping clients with issues regarding observational findings, 483s and GMP-type issues.” (Fleischer Jan. 7, 2020 Dep. 24:8–15.) He further stated, “I even published a paper on CGMPs, so I’m very familiar with CGMPs.” (Id. at 128:17–19.) He has “read a lot of papers and have read guidances” to give him “an overall familiarity with what CGMPs are.” (Id. at 129:2–4.) Thus, standing alone, Dr. Fleischer’s opinion on the meaning of a cGMP and FDA Form 483 is admissible.⁵ Although Dr. Patel and Mr. LoPiccolo may have a greater expertise on that subject, that fact does not render Dr. Fleischer’s independent opinion subject to exclusion. See Pineda v. Ford Motor Co., 520 F.3d 237, 244 (3d Cir. 2008). (“[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.” (quotations omitted)). Indeed, the fact that Dr. Fleischer confirmed that opinion with two qualified colleagues could bolster its reliability. To the extent the DPPs believe that Dr. Fleischer has no independent knowledge to support his opinions, that can be the subject of cross-examination and will go to the weight, not the admissibility of his expert report.

⁵ Dr. Fleischer’s qualifications render this case distinguishable from the Tenth Circuit case of TK-7 Corp. v. Estate of Barbouti, 993 F.2d 722 (10th Cir. 1993) on which the DPPs rely. In that case, the court found that an expert opinion was inadmissible where the expert “failed to demonstrate any basis for concluding that another individual’s opinion on a subjective financial prediction was reliable, other than the fact that it was the opinion of someone he believed to be an expert who had a financial interest in making an accurate prediction.” Id. at 732.

Unlike TK-& Corp., Dr. Fleischer is qualified and has indicated that he independently reached his opinion. He merely confirmed and corroborated that opinion with Dr. Patel and Mr. LoPiccolo.

2. Testimony About the “Go Live Requirement” For the Generic ANDAs

The DPPs’ also challenge Dr. Fleischer’s opinion on the “Go-Live” requirement for generic ANDAs. As set forth above, Plaintiffs’ expert, Deborah Jaskot, opined that if the generics’ REMS “were approved by FDA between August 22, 2012 and September 1, 2012, there were no other regulatory hurdles or obstacles that would have prevented final approval of these two ANDAs during that same time frame.” (Jaskot Rep. ¶ 18.) In rebuttal, Dr. Fleischer opined that the BTOD [Buprenorphine-containing Transmucosal product for Opioid Dependence] REMS required a website and call center that could “Go-Live”—*i.e.*, be operational or functioning—prior to the launch of the ANDAs. However, according to Dr. Fleischer neither the website nor the call center were operational until March 5, 2013. (Fleischer Rep. ¶ 93.) He went on to explain:

94. The BPMG [Buprenorphine Products Manufacturers Group] contracted with PPD [an outside vendor] to develop the website and call center components of the REMS program. It took considerable time for the BPMG to select PPD as its “go-live” vendor. And, it took several months (from July 2012 to late December 2012) to finalize the PPD-BPMG agreement regarding the development, operation, and management of the BTOD REMS. . . .

95. The PPD-BPMG agreement anticipated that the launch of the BTOD REMS “go-live” website and call center would occur roughly one to two months after FDA’s approval of the BTOD REMS. . . .

96. “In February 2013, the BPMG members requested that PPD expedite the timelines for launch of the call center and website ‘to occur on March 1 or as soon as the PPD develops and receives approval of material from the BPMG.’” (Affidavit of Robin Kinard ¶ 34 (quoting PPD000001718).) The BPMG and PPD eventually implemented changes so that the website and call center could be operational on March 5, 2013. . . .

97. Robin Kinard, PPD’s Senior Oversight Lead for the BTOD REMS project, even admits that “[g]iven the timing of FDA’s final approval on February 22, 2013, PPD and the generic manufacturers could not realistically have completed all tasks necessary for the program’s operational launch substantially sooner than the actual ‘go-live’ date of March 5, 2013.” (Affidavit of Robin Kinard ¶ 19.)

98. Regardless of the approval of the REMS, the BPMG generic manufacture[r]s could not have launched their products prior to March 5, 2013 because the FDA-required website and call center were not ready until that date. The original agreement between PPD and the BPMG also anticipated an even later “go-live” date. And importantly, the website and call center issues were not related to any other ANDA deficiency and delayed the launch date of Amneal’s product independently of the other deficiencies.

(Fleischer Rep. ¶¶ 94–98.)

The DPPs claim that Dr. Fleischer is unqualified to offer an opinion on this issue. They assert that Dr. Fleischer applied no regulatory expertise, experience, analysis, or methodology, and that he admitted to possessing no education or experience in the areas of website and call center design or launch. The DPPs also contend that Dr. Fleischer’s opinion is directly contradicted by Robin Kinard, the Senior Director of Risk Management at PPD, who is in charge of the website and call center launch and explained that some of the necessary “go-live” work was dependent on first getting REMS approval from the FDA.

According to Defendant, however, unrefuted evidence established that the FDA required a fully operational website and call center before any generic tablet was put into interstate commerce. (Def.’s Opp’n, Exs. 10, 11, 17.) Defendant asserts that Dr. Fleischer, who has almost forty years of experience in the drug approval realm, is qualified to provide the logical opinion that when the FDA conditions a company’s product launch on a “fully operational” REMS (including a website) and call center, generic manufacturers cannot sell their products until these elements were operational. Such an opinion, according to Defendant, does not require or even relate to expertise in website and call center design or launch, as suggested by the DPPs.

I agree with Defendant and find Dr. Fleischer qualified to render this opinion on the “Go-live” requirement. Daubert’s focus is on whether an expert’s qualifications provide a foundation for the witness to testify meaningfully on a given matter. Dr. Fleischer holds a Ph.D. in

Pharmacology. (Fleischer Rep. ¶ 4.) His work “focuses on advising both brand and generic drug companies on the Food and Drug Administration’s (‘FDA’) regulatory process for the approval of innovator and generic drugs, including scientific and regulatory issues relating to the submission and review of applications to the FDA, including new drug applications (‘NDA(s)’) and abbreviated new drug applications (‘ANDA(s)’).” (*Id.* ¶ 5.) He has advised clients on regulatory issues relating to the submission and review of at least 400 NDAs and ANDAs. (*Id.* ¶ 6.) Dr. Fleischer also worked at the FDA for seventeen years, most recently as the Director of the Division of Bioequivalence, Office of Generic Drugs. (*Id.* ¶ 8.) He has “wide-ranging experience with FDA regulations, policies, and guidelines” as well as “experience with the specific procedures for filing, amending, and supplementing ANDAs filed under 21 U.S.C. § 355(j) and related statutes.” (*Id.* ¶ 14.)

Such extensive experience with the FDA regulatory process for both generic and brand drugs renders him sufficiently qualified to opine that the generics’ failure to have a live and running website and call center prior to March 5, 2013 would have, under the FDA’s regulations, precluded the generics from launching their products prior to that date. See generally In re Flonase Antitrust Litig., 907 F. Supp. 2d 637, 642 (E.D. Pa. 2012) (finding that expert’s “lifelong experience in the field of food and drug regulation demonstrates that he is well-equipped to discuss the FDA’s processes for responding to citizen petitions, and that he is qualified to opine on whether a sophisticated petitioner like GSK could have reasonably expected to succeed in changing FDA policy with its petitions.”). Such an opinion does not require, as the DPPs contend, any expertise in website or call center design and launch. Indeed, Dr. Fleischer does not attempt to discuss what was required for the website and call center to “go live” or to posit that the generics’ website/call center itself was not ready. Rather, he simply relies on the undisputed fact that the generics’ website and call center were not ready to “go live” until, at the earliest March 5, 2013. (See Def.’s Opp’n, Ex. 14, Aff. of Robin Kinard (“Kinard Aff.”) ¶ 32 (“Although the BTOD REMS program was approved

on February 22, 2013, the program was not operational until a number of days later . . . until March 5, 2013.”) He then applies his knowledge of well-settled FDA regulations to state that “the BPMG generic manufacture[r]s could not have launched their products prior to March 5, 2013 because the FDA-required website and call center were not ready until that date.” (Fleischer Rep. ¶ 98.) Such an opinion could be helpful for a jury to understand the regulatory obstacles that might have prevented the generics from launching their products.

I also find no merit to the DPPs’ argument that Dr. Fleischer’s opinion is directly contradicted by Robin Kinard, who was in charge of actually developing the website and call center. As noted above, the DPPs argue that Ms. Kinard stated that if the generics were approved earlier, the website could have gone live earlier because some of the necessary “go-live” work was dependent on first getting REMS approval from the FDA. (Def.’s Opp’n, Ex. 29, Dep. of Robin Kinard (“Kinard Dep.”) 115:1–25.) In her affidavit, however, Ms. Kinard admitted that the website and call center “were not operational until March 5, 2013.” (Kinard Aff. ¶ 32.) Indeed, she averred that the original Project Addendum for the BTOD Rems did not anticipate launch of the website and call center components until one to two months after FDA approval of the REMS program. (*Id.* ¶ 33.)

Moreover, a closer look at Ms. Kinard’s testimony reveals that she was more equivocal about the ability to go live earlier with FDA approval because she had not looked back to where the project was at the relevant time:

Q. Was PPD in a position—just assume that the REMS had been approved earlier, during some earlier period of time, okay? Say the REMS had been approved by the FDA according to, well, your original timeline, at the end of September. Could you have gone live prior to March 5, 2012?

A. I feel like I cannot answer that hypothetically because I’d have to know where we were in the process of that time, what was built, what wasn’t built. I just don’t feel like I can just answer that

hypothetically. But I would say, if we were approved earlier, would we have probably have gone live earlier, yes.

(Kinard Dep. 115:13–25.)

Dr. Fleischer did, in fact, look back to that earlier time and noted evidence that BPMG did not begin work on the Go-Live requirements until the summer of 2012, and the website was an ongoing issue through August 2012. (Fleischer Sur-Rebuttal Rep. ¶ 22.) He further remarked that, even on February 15, 2013—a week prior to the generics’ ANDA approval—the generics could not commit to a timeframe for completing the REMS website. (*Id.*) Based on that information, Dr. Fleischer opined that he “did not believe that the BPMG could have launched the mandatory website and call center in 1.5 weeks had Amneal and Actavis obtained ANDA approval in August or September 2012.” (*Id.*) Given the less than certain nature of Ms. Kinard’s testimony, I cannot find that it undermines Dr. Fleischer’s report, such that I would exclude this opinion under Daubert. To the extent that the DPPs can prove—either through Ms. Kinard’s trial testimony⁶ or otherwise—that the generics’ websites and call centers could have, in fact, been operational prior to March 5, 2013, those facts can be used on cross-examination to test the validity of Dr. Fleischer’s opinion.

B. Opinions of Sheldon Bradshaw

The DPPs next move to exclude opinions offered by Defendant’s expert Sheldon Bradshaw, who Defendant offers in rebuttal to the DPPs’ expert, Professor Patricia Zettler.

⁶ The DPPs contend that Dr. Fleischer admitted at deposition that because Ms. Kinard’s company, PPD, was in charge of developing and launching the website and call center, Ms. Kinard was in a better position to testify as to how quickly the go-live requirements could have been completed. (Fleischer Jan. 7, 2020 Dep. 121:4–8.)

However, an expert will not be excluded “simply because [the court] does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.” Holbrook v. Lykes, Bros. S.S. Co., 80 F.3d 777, 782 (3d Cir. 1996). Rather, in the event that Dr. Fleischer and Ms. Kinard offer conflicting testimony on this subject at trial, it will be within the province of the jury to weigh their credibility, taking into consideration Dr. Fleischer’s admission that Ms. Kinard is more qualified.

The DPPs' expert, Professor Zettler, opines in part that (a) Defendant's conduct during the development of the shared REMS ("SSRS") for Suboxone and generic equivalents delayed approval of the SSRS until February 2013; and (b) it was false and misleading, in violation of various laws and regulations, for Defendant to claim that Suboxone film was less prone to misuse and better avoided pediatric exposures than Suboxone tablets. Mr. Bradshaw responds that (a) Defendant did not unduly delay in commencing SSRS negotiations with BPMG [Buprenorphine Products Manufacturers Group] generic manufacturers in First Quarter 2012; (b) Defendant's negotiating positions and conduct during SSRS negotiations in 2012 were objectively reasonable under the circumstances and did not delay generic entry; and (c) Defendant's marketing claims regarding tablets and film complied with FDA promotional standards.

The DPPs' challenge to Mr. Bradshaw's opinions is two-fold. First, they contend that Mr. Bradshaw impermissibly opines on the state of mind and subjective intent of Defendant and its employees during the SSRS negotiations. Second, they claim that Mr. Bradshaw improperly speculates that the FDA must have found that certain of Defendant's marketing materials complied with FDA regulations because it did not issue a Warning Letter or Untitled Letter.

1. Opinions as to Good Faith and State of Mind

The DPPs first argument challenges certain isolated portions of Mr. Bradshaw's 110-page report that project subjective motivations onto Defendant's actions. Three sets of statements are at issue:

#1 – Section III.E - “Reckitt Acted in Good Faith During SSRS Negotiations,”

214. Plaintiffs claim that Reckitt acted in bad faith by raising its various “gating” issues during SSRS negotiations with the BPMG generic manufacturers. However, the evidentiary record clearly negates such claims.

215. Robin Kinard, PPD's Senior Oversight Lead for the BTOD REMS project, was aware of Reckitt's SSRS positions and witnessed

first-hand Reckitt's negotiation conduct with the BPMG generic manufacturers. She observed that: "Communications among BPMG members included debate regarding the contemplated REMS program. At times member companies disagreed regarding the merits of particular proposals. However, I do not recall any communications that I considered to be disrespectful or unprofessional. I also do not believe any participants in the BPMG meets were acting in bad faith. It is normal for manufacturers engaged in these kinds of joint projects to each advance its own positions. [sic] My observation is that each of the participants in the BPMG, including both Reckitt and the generic manufacturers, acted in good faith throughout the process."

216. Similarly, Kellie Taylor of the FDA also recognized that neither Reckitt nor the BPMG manufacturers were clearly to blame for the breakdown of SSRS negotiations. She testified that she "was aware of there being an inability to come to a single shared system REMS agreement" among the BPMG members, but felt "the cause of that inability . . . could [have been] on either side of the aisle . . . cooperation issues in a general sense."

217. Based on the testimonies of Ms. Kinard and Dr. Taylor, and my review of the contemporaneous documents, it is clear to me that the Reckitt's SSRS negotiation positions were taken in good faith and were not the sole cause of the BPMG's inability to create a single shared REMS system with Reckitt.

(Chiorean Decl., Ex. 4, Report of Sheldon Bradshaw ("Bradshaw Report"), ¶¶ 214–17 (internal citations omitted) (collectively "§ III.E").)

#2 – Other References to Defendant's "Good Faith" During SSRS Negotiations

- As Reckitt began to negotiate in good faith with the Generic ANDA Holders . . .
- Reckitt did not mislead FDA regarding . . . its willingness to negotiate with the ANDA applicants in good faith.
- Throughout the SSRS negotiations, Reckitt communicated to the FDA honestly about both the progress of its negotiations with the generic manufacturers and, despite its initial disinclination to participate in SSRS negotiations, the fact that it was negotiating in good faith with the ANDA applicants once it committed to participate in SSRS negotiations and not trying to drag out the negotiations.

(Id. ¶¶ 115, 222, 223 (collectively the "other good faith statements").)

#3 – Statements Regarding Subjective Motivations of the Parties

- The generic manufacturers preferred to save money.
- On June 13, 2012, Reckitt—concerned how the generic manufacturers had reneged on their promise to share up front cost for the BPMG REMS—sent a memorandum . . . to the FDA setting forth its concerns . . .
- To ensure that the generic manufactures [sic] took patents [sic] safety as seriously as Reckitt itself, Reckitt requested that the BPMG commit to signing a safety mission statement.
- The uncertain nature of the law of product liability made it important to try to gain a measure of clarity regarding how legal liability and litigation costs would be apportioned.
- When Reckitt was the sole manufacturer of [buprenorphine] products the company could influence the safety protocols in the opioid addiction disease space.

(*Id.* ¶¶ 119, 162, 167, 204, 208 (collectively, the “subjective motivation statements”).)

The DPPs now contend that these state of mind and intent opinions are inadmissible because, as an expert, Mr. Bradshaw cannot offer testimony regarding someone else’s state of mind. They posit that Mr. Bradshaw’s reliance on Ms. Kinard’s Affidavit is improper because Ms. Kinard admitted in deposition that she was not privy to much of the SSRS negotiations and could not speak to Defendant’s internal discussions.

Defendant agrees with the DPPs that no expert may opine on the state of mind and subjective intent of Defendant, its employees, or any third parties. Defendant further represents that Mr. Bradshaw “will not be testifying to anyone’s subjective state of mind,” and agrees that references to “good faith” are inadmissible. (Def.’s Opp’n DPPs’ Mot. 18.) Nonetheless, Defendant presses that Mr. Bradshaw should be able to testify as to objective facts.

It is well settled that experts may not provide testimony concerning “the state of mind” or “culpability” of defendants, corporations, regulatory agencies, and others. Wolfe v. McNeil-PPC,

Inc., 881 F. Supp. 2d 650, 661–62 (E.D. Pa. 2012); see also Deutsch v. Novartis Pharms. Corp., 768 F. Supp. 2d 420, 448 (S.D.N.Y. 2011) (precluding an expert witness from testifying as to pharmaceutical company’s bad faith). Indeed, the question of intent constitutes a “‘classic jury question and not one for experts.’” Robinson v. Hartzell Propeller, Inc., 326 F. Supp. 2d 631, 648 (E.D. Pa. 2004) (citations omitted); see also In re Rosuvastatin Calcium Patent Litig., MDL No. 08-1949, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009) (“Generally, expert witnesses are not permitted to testify regarding ‘intent, motive, or state of mind, or evidence by which such state of mind may be inferred.’”) (internal quotations omitted).

Here, several of Mr. Bradshaw’s conclusions exceed these bounds. First, the entirety of Section III.E of his report is inadmissible because Mr. Bradshaw simply recites statements by Robin Kinard and Kellie Taylor to reach the conclusion that “Reckitt’s SSRS negotiation positions were taken in good faith and were not the sole cause of the BPMG’s inability to create a single shared REMS system with Reckitt.” Such an opinion regarding intent is improper. (Bradshaw Rep. ¶ 217.) While Ms. Kinard’s and Ms. Taylor’s observations may potentially be introduced through their individual testimony, the jury must be free to draw its own conclusion about the import of those observations.

As to Mr. Bradshaw’s “other good faith statements,” I also find that they are inadmissible. These statements, embedded in longer paragraphs within Mr. Bradshaw’s report, impermissibly ascribe to Defendant a subjective intent to negotiate in good faith with the generic ANDA applicants.

Finally, as to the alleged “subjective motivation statements,” Mr. Bradshaw may certainly testify factually about various subjects such as potential litigation risks from safety concerns and factors that drug manufacturers consider in issuing public warnings about products. As such, wholesale exclusion of these statements is not warranted. Mr. Bradshaw cannot, however, suggest to the jury how those facts bear on the parties’ subjective thought processes. Defendant has

acknowledged this basic evidentiary rule and emphasized that Mr. Bradshaw’s intended testimony will not delve into these subjects. Should the DPPs believe, however, that any question posed to Mr. Bradshaw at trial goes beyond permissible inquiries, they may of course object at that time.

2. Opinions About the FDA’s Conclusions

The DPPs next argue that Mr. Bradshaw should not be permitted to mislead the jury about what the FDA did nor did not conclude about Defendant’s marketing efforts. On this topic, Mr. Bradshaw’s report states:

263. The record suggests that [the FDA’s Office of Prescription Drug Promotion (“OPDP”)] was in fact specifically asked (by FDA officials reviewing Reckitt’s Citizen Petition) to review at least one exemplar of Reckitt’s promotional messaging. . . .

264. Importantly, no action was taken by OPDP following this consultation (and, to date, Reckitt has not received either an untitled or warning letter concerning its marketing claims since the introduction of Suboxone Film in 2010). Based on my experience, this means that OPDP did not conclude that the materials violated FDA’s advertising regulations. As Plaintiffs’ expert correctly noted, when OPDP determines that promotional materials violated FDA’s advertising regulations, it would send the drug sponsor a warning or untitled letter.

(Bradshaw Rep. ¶¶ 263–64 (emphasis added).)

The DPPs contend that, to the extent Mr. Bradshaw testifies that “no action was taken” by the FDA or OPDP, his opinion is false and misleading because the FDA took enforcement action against Defendant through a criminal investigation and resulting grand jury indictment based, in part, on Defendant’s Suboxone marketing efforts. If Mr. Bradshaw’s opinion is not excluded, the DPPs urge that a fair cross-examination of Mr. Bradshaw on his “cherry-picked account of the FDA’s enforcement history” requires that evidence of the criminal investigation and indictment be admitted. (DPPs’ Mot. 16.)

This argument is not the proper subject for a Daubert motion. The DPPs do not challenge Mr. Bradshaw's qualification to render this opinion, do not establish that Mr. Bradshaw's method in reaching the opinion is unreliable, and offer no challenge to the "fit" or relevance of this testimony to this case. Instead, the gist of the DPPs' motion is that *if* Defendant elicits testimony from Mr. Bradshaw on this topic, then the DPPs must be permitted to cross-examine Mr. Bradshaw on the criminal investigation and indictment to which the FDA contributed. This issue is better suited for a motion *in limine*.

Any mention of criminal proceedings could be highly prejudicial. Defendant, however, should be on notice that pressing Mr. Bradshaw to state that the FDA took no action in response to Defendant's promotional materials could open the door to appropriate rebuttal.

IV. THE STATES' MOTION TO EXCLUDE DR. DOLORES CURTIS

The States have filed a Daubert motion seeking to preclude the expert testimony of Defendant's expert Dr. Dolores Curtis. Dr. Curtis is President of Curtis Analytic Partners, Inc. ("CAP"), which specializes in marketing research and provides consulting services to small, mid-size, and large organizations in the healthcare business. (States' Mot., Ex. R, Rep. of Dolores Curtis ("Curtis Rep."), ¶ 1.) Dr. Curtis's report notes that, from 2004 through 2013, CAP provided both qualitative and quantitative marketing research services to Defendant. In connection with those services, CAP ran numerous marketing studies, many of which were focused on Suboxone film and tablets, in order to gauge prescribing and user preferences. (Id. ¶¶ 16–17.) These studies were conducted with physician prescribers and non-prescribers of Suboxone, as well as patient users and non-users. (Id. ¶ 18.) Based on the results of those studies, Dr. Curtis now offers three main opinions: (1) patients and physicians prefer Suboxone film over tablets; (2) the fact that film was often less expensive than generic tablets caused patients to favor Suboxone film; and (3)

Defendant's disparagement of tablets over alleged safety concerns had a "relatively minor" impact on patient and physician preferences for film.

The States seek to preclude the entirety of Dr. Curtis's proposed testimony under all three of the Daubert factors. Primarily, they assert that she is not qualified to render the opinions proposed, and also contend that Dr. Curtis cannot reliably evaluate the methodology and statistical limitations of her surveys. Finally, the States posit that Dr. Curtis's testimony fails to "fit" under Daubert because it does not assist the trier of fact.

1. Qualifications

The States first contend that Dr. Curtis is not qualified to render the opinions proposed. She is a trained school psychologist with a master's degree in education, a graduate degree in school psychology, and a doctorate in philosophy. Currently, she owns a business focused on marketing surveys. According to the States, she has no statistical analysis training or experience, was uninvolved in the formation of the CAP surveys used, relied on others to do statistical analysis, does no such statistical analysis herself, and is not qualified from any medical perspective. The States posit that nothing in this background qualifies her to testify as an expert with respect to the accuracy of the methodologies used in the surveys, the statistical accuracy of the surveys, or the characteristics of Suboxone film or other drugs.

Defendant responds that Dr. Curtis easily meets the minimal standards of qualification under Rule 702. It points out that Dr. Curtis founded CAP in 1991, and she and her company have been conducting surveys ever since. In addition to the dozens of studies for Defendant alone, CAP has conducted hundreds of studies for other clients. Dr. Curtis herself played an active role in her company's projects, discussing project design, methodologies, timing, and execution with her staff project leads and reviewing all final reports prior to transmittal. Defendant presses that Dr. Curtis's

decades of experience working on consumer research studies and surveys qualifies her to evaluate and opine regarding findings in the surveys at issue here.

“Qualification requires ‘that the witness possess specialized expertise.’” Pineda v. Ford Motor Co., 520 F.3d 237, 244 (3d Cir. 2008) (quoting Schneider ex re. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003)). As noted above, however, there is a liberal policy of admissibility and the Third Circuit has held that a “broad range of knowledge, skills, and training qualify an expert.” Id. (quoting Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741–42 (3d Cir. 1994)). The basis of this specialized knowledge “can be practical experience as well as academic training and credentials.” In re Mushroom Direct Purchaser Antitrust Litig., No. 06-620, 2015 WL 5767415, at *3 (E.D. Pa. July 29, 2015) (internal quotations omitted). “If the expert meets liberal minimum qualifications, then the level of the expert’s expertise goes to credibility and weight, not admissibility.” Kannankeril v. Terminix Int’l, 128 F.3d 802, 809 (3d Cir. 1997) (citing Paoli, 35 F.3d at 741); see also Hammond v. Int’l Harvester Co., 691 F.2d 646, 653 (3d Cir. 1982) (affirming admission of an expert on defective nature of farm equipment even though he had no formal schooling on the subject, but he had worked selling automotive and mechanical equipment, including agricultural equipment, and had taught automobile repair and maintenance at a high school).

I find that Dr. Curtis meets the liberal minimum qualifications to offer her statistical expert opinion on whether patients and physicians prefer Suboxone film over tablets, the impact of pricing of film and tablets on patient preference, and the impact of Defendant’s safety messaging on patient and physician preferences for film. First, notwithstanding the states challenge to her lack of specialized education in statistics and the absence of a license at CAP for SPSS, (see States’ Mot., Ex. D, Dep. of Dolores Curtis (“Curtis Dep.”), 18:5–9, 32:4–15), Dr. Curtis’s report explains:

My statistical training was during my master's and doctoral studies. At that time, I learned about and was trained on the utilization of psychological and counseling techniques requisite for evaluative purposes. On the quantitative side, I was schooled in the Statistical Package for Social Sciences ("SPSS"), as well as other survey-based statistical techniques including analysis of variance ("ANOVA"), chi-square, cross tabulations, P and F values, conjoint analysis, and univariate analyses. As such I am qualified as an expert witness.

(Curtis Rep. ¶ 19.)

At her deposition, Ms. Curtis testified that she understood how to do the statistical analysis and had training, despite the fact that she did not have broad educational background in statistics. (Curtis Dep. 132:2–21.) She admitted that she often plugged numbers into online tools, which "anybody can do," but clarified that the online tools were well-validated. (*Id.* at 132:22–133:25.) A jury may certainly find that, given Dr. Curtis's lack of more formal statistical training, her opinion is entitled to less weight. That factor, however, does not render her unqualified for purposes of exclusion under Daubert.

Second, as to her experience, the States press that Dr. Curtis was uninvolved in the formation of the surveys and is unqualified to offer expert opinion on the propriety of the methodologies utilized in the survey process. They posit that she did not consult with a statistician and that she personally does no statistical analysis, is not an expert in survey design or statistics, relies on the expertise of the in-house-lead of quantitative work, and only generally reviews what is suggested in research proposals. (*Id.* at 37:25–38:4, 39:14–19, 79:6–15.)

Dr. Curtis's report, however, suggests a broader involvement in statistical analysis. Dr. Curtis is the founder and, since 1991, has been the President of CAP. In that role, she oversees and assumes responsibility "for all qualitative and quantitative marketing research. This includes determining research design (along with [her] colleagues), establishing study leads, and assigning appropriate support staff and personal involvement in selected qualitative studies as appropriate."

(Curtis Rep. 2.) She is accountable for all research aspects for studies in which she is personally involved and for studies implemented by other senior staff, and she is the key lead researcher on the majority of the qualitative studies conducted by CAP. (Id. ¶ 3.) As Dr. Curtis described her role:

After initially creating the idea of the business, I put together appropriate resources and key personnel staff that would allow the company to be successful and make our services known in the pharmaceutical healthcare marketplace. I also wrote or co-wrote every proposal that left CAP, including those for Reckitt. Prior to writing proposals, I discussed the potential projects with the CAP leads who would be assigned the projects should CAP be awarded the work. These discussions covered decision-making about appropriate methodologies, timing requirements, and overall execution responsibilities. In other words, I was always aware of how each study was designed, sampled, and undertaken. I was also regularly apprised of the status of each study. Regarding review of screeners or questionnaires for any of the quantitative studies where Dr. Piano was spearheading quantitative work, his co-lead on the study during that time, CAPs Vice President, Lori Gittleman, would address questions and/or review screeners or survey instruments as necessary. If there was a specific question or concern, I reviewed discussion outlines and survey instruments. I also typically reviewed all final reports prior to sending to end clients to ensure they met the research goals.

(States' Mot., Ex. S, Curtis Rebuttal Rep., ¶ 10.)

Finally, as to Dr. Curtis's reliance on her employees for statistical work, it is well recognized that, "[a]n expert witness is permitted to use assistants in formulating his expert opinion." Dura Auto. Sys. of Indiana, Inc. v. CTS Corp., 285 F3d 609, 612 (7th Cir. 2002). "Where the expert was directly involved with the research, analysis or drafting of the report, even with substantial assistance from a colleague or associate, his involvement in and knowledge of the report are matters of weight, not admissibility. Lee Valley Tools, Ltd. v. Indus. Blade Co., 288 F.R.D. 254, 266 (W.D.N.Y. 2013). Under these liberal rules of qualification, I find that Dr. Curtis indeed possesses

the expertise necessary to testify as an expert on subject of consumer research studies and surveys.⁷ The arguments raised by the States are certainly fodder for cross-examination and may be fair grounds for challenging Dr. Curtis's credibility at trial. They are not, however, a basis on which to exclude her testimony entirely.

2. Reliability

The States next posit that the underlying surveys by Curtis Analytic Partners, Inc. ("CAP Reports") are fundamentally flawed, and therefore unreliable.

As set forth above, the reliability restriction requires that the testimony be based upon "the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'" and that the expert have "'good grounds' for his or her belief." Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) (quotations omitted). The rule does not require the party proffering the expert to demonstrate that the expert's assessment is correct. Paoli R.R. Yard, 35 F.3d at 744. Rather, the party need only demonstrate "by a preponderance of the evidence" that the expert's opinion bears adequate indicia of reliability. Id. A flaw in methodology does not automatically disqualify an expert opinion; the flaw must be of such substance to create a lack of "good grounds" for the expert's conclusions. Id.

Dr. Curtis's report first provides an overview of the best practices used in a marketing research arena including: having specific goals, selecting samples that well represent the population to be studied, taking great care in matching question format and wording to the concepts being measured and the population being studied, pretesting questionnaires and procedures, using

⁷ The States also argue that Dr. Curtis is also not qualified to draw conclusions about patients' or physicians' preferences from a medical perspective because she is not an expert in opioid use disorder and has no medical training. Defendant, however, does not offer Dr. Curtis as a medical expert, but rather as a statistical and consumer/marketing research expert. As such, I need not address this argument.

appropriate statistical analytic and reporting techniques, considering alternative data beyond a survey, using designs that balance costs with errors, training interviewers carefully on interviewing techniques and the subject matter of the survey, checking quality at each stage, maximizing cooperation or response rates within the limits of ethical treatment of human subjects, and developing and fulfilling pledges of confidentiality given to respondents. (Curtis Rep. ¶ 20 & n.6.) Dr. Curtis then goes on to discuss how the CAP studies met these best practices and explains that “[t]he research used random sampling of the target patient population and applied factor analysis, correlation, cluster analysis, Likert scales and open and closed-ended questions to address study objections.” (Id. ¶¶ 21–24.) Finally, the report describes the primary research studies in detail, including the methodologies, sample sizes, relevant conclusions, and how Plaintiffs’ experts misused these studies. (Id. ¶¶ 58–131.) The report also describes ten secondary supportive studies that bolster the primary studies. (Id. ¶¶ 132–47.)

Dr. Curtis then offers three opinions based off of the CAP studies. First, relying on seven different studies, including “the top five highest-powered physician and patient CAP studies,” she opines that patients and prescribing physicians prefer Suboxone film over tablets. (Id. ¶¶ 27, 37.) Those studies had sample sizes of up to 500 participants, spanned a time frame of 2009 to 2013, and encompassed the views of both patients and physicians. (Id. ¶¶ 37, 40.) Dr. Curtis notes that the preference for film was largely based on two key factors, dissolution time and improved taste. (Id. ¶¶ 30–36.) Thereafter, Dr. Curtis looked beyond the CAP research studies and considered clinical trials, a 2012 peer-reviewed article, and surveys conducted by another marketing research firm, all of which confirmed her conclusion that Suboxone film was a “dominantly preferred first-line therapy for most opioid-dependent patients.” (Id. ¶¶ 154–61.)

Dr. Curtis’s second opinion posits that, aside from patients’ and physicians’ preference for film, “[t]he combination of the generics’ failure to offer a substantially cheaper medication with

Reckitt’s cost-saving coupon program made pricing preferences point in the same direction as product preferences—toward Film.” (*Id.* ¶ 42.) Dr. Curtis cites to two January 2011 studies—one of 40 physicians and one of 300 physicians—which reflected that the most common reason for physicians prescribing the film was due to the coupon savings program. (*Id.* ¶ 47.)

Dr. Curtis’s last opinion observes that “[w]hile the preference for and pricing of Film were the key drivers of treatment decisions, data indicates that any safety messaging associated with Film had a relatively minor influence on physicians’ and patients’ choice of prescriptions.” (*Id.* ¶ 49.) This opinion relies on various preference studies among both physicians and patients which gauged what factors made film more attractive over tablets, and asked study participants to rank these factors. These studies, according to Dr. Curtis, consistently found that safety features such as child-resistant packaging and ease of abuse/misuse/diversion ranked lowest among the considerations. (*Id.* ¶¶ 49–57.)

The States now identify three purported flaws in Dr. Curtis’s methodology, which they claim undermines the reliability of her opinions.

a. Bias in Methodology for Selecting Patients

The States first contend that participant selection in the various CAP surveys were deliberately biased in favor of those who preferred film. They claim that Dr. Curtis admitted that, with respect to one of the surveys at issue, someone who is happy with their Suboxone tablet and has never taken film would never make it into the survey. (Curtis Dep. 256:30–275:12.) The States then note that this sampling injects bias into the results,⁸ which render them unsuitable for making inferences about overall preference for film.

⁸ (See States’ Mot., Ex. B, Expert Rebuttal Report of Ernst Berndt (“Berndt Rebuttal Rep.”) ¶¶ 76–79 (“For example, the 2011 Suboxone Film Post Launch Monitor excludes potential respondents that never took Film, so their preferences for taking and remaining on tablets are also excluded from the analysis. . . . This introduces sampling bias in the results, because the outcomes

The States also criticize Dr. Curtis for not identifying generally accepted methods to reach her sweeping inferences about entire patient and physician populations. According to States' expert Nicholas Jewell, Dr. Curtis "does not demonstrate for *any* of the surveys she cites why the sample sizes were chosen as they were, or how the selected group of participants compare to the population at large, or how CAP accounted for response bias." (Jewell Rep., ¶ 60 n.87.) Moreover, States' expert Dr. Berndt opines that Dr. Curtis provides "little to no explanation of how the responses to these surveys were processed," including "the process of content analysis and response interpretation, thematic[] organization, employment of coding mechanisms, [and] thresholds of significance for anecdotal conclusions." (Berndt Rebuttal Rep. ¶ 81.) Absent explanations to address these concerns, the States posit that the quantitative methods CAP actually used remain a mystery.

The States' argument is flawed in several respects. Primarily, the States' criticism regarding bias in the reports is leveled at only a handful of the surveys relied upon by Dr. Curtis. Assuming *arguendo* that this criticism is accurate and creates bias in those identified surveys, this deficiency does not impact the entirety of Dr. Curtis's report, which relies on more than thirty different studies. For example, several of the surveys focused solely on *physician* samplings and why physicians prescribed either film or tablets. (Curtis Rep. ¶ 27–30.) Thus, the States' contention that a certain *consumer* population was excluded would be irrelevant to such studies. Moreover, in one major study involving a sampling of 500 consumers, 377 individuals were currently using film with past

are based upon a non-representative sample of the population that would, on average, already exhibit a preference for Film."); States' Mot., Ex. J, Expert Report of Nicholas Jewell ("Jewell Rep."), ¶ 63 ("It is clear that physicians' opinions and practices were the driver in providing film experience for a significant number of respondents, a factor that has an indeterminate influence on patients' responses. However, it is reasonable to assume that this phenomenon will bias preference results in favor of film as the imposition of film by a physician brings with it the implicit (if not explicit) endorsement of the physician, potentially affecting a patient's preference for one formulation over the other."))

tablet experience, 89 had past film experience of at least one week, and only 34 had started on the film with no tablet experience. (Curtis Rep., App’x B.19. at 5.) Finally, to the extent the States challenge surveys for not including patients who had never tried film, such a criticism would not impact the viability of a survey that sought information about what patients and doctors liked and did not like about tablets. (See Curtis Rep., App’x B.6, at 24 (physicians and patients did not like taste/aftertaste of tablets, the difficulty of keeping tablets under the tongue, or the fact that tablets break apart in bottles).)

More importantly, “mere technical flaws” in a survey’s design or execution go to the weight to be afforded to the survey, not its admissibility. Citizens Fin. Grp., Inc. v. Citizens Nat’l Bank of Evans City, 383 F.3d 110, 121 (3d Cir. 2004); see also Karlo v. Pittsburgh Glass Works, LLC, 849 F.3d 61, 83 (3d Cir. 2017) (“The question of whether a study’s results were properly calculated or interpreted ordinarily goes to the weight of the evidence, not to its admissibility). Imperfections in the extent of a survey’s universe—*i.e.*, overinclusivity or underinclusivity—generally constitute technical flaws that do not undermine a survey’s admissibility. Koninklijke Philips Elecs. N.V. v. Hunt Control Sys., Inc., No. 11-3684, 2016 WL 3545529, at *6–7 (D.N.J. June 29, 2016). Stated differently, while a survey that excludes the *entire* relevant population may be so unreliable as to be inadmissible, see, e.g., Citizens Fin. Grp., 383 F.3d at 118–21 (upholding exclusion of consumer survey where interviewer polled consumers not located in the geographic area relevant to the facts of the case), a survey that is simply underinclusive or has other flaws in sampling remains admissible but subject to challenge. See, e.g., Hartle v. FirstEnergy Generation Corp., Nos. 08-1019, 08-1025, 08-1030, 2014 WL 1317702, at *6 (W.D. Pa. Mar. 31, 2014) (“Defendant’s arguments with respect to insufficient pretesting, improper information gathering, confusion by respondents, nonrepresentative and nonrandom sampling, hypothetical bias, error rate, and inconsistent and unconventional statistical analysis are ‘technical flaws’ that go to the weight rather than

admissibility of the survey.”); Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1143 (9th Cir. 1997) (finding that alleged leading questions and geographic limitation on survey respondents “go only to the weight, and not the admissibility, of the survey”); Jellibeans, Inc. v. Skating Clubs of Ga., Inc., 716 F.2d 833, 844–45 (11th Cir. 1983) (holding that “(1) poor sampling; (2) inexperienced interviewers; (3) poorly designed questions; and (4) other errors in execution” constituted “technical deficiencies” affecting the survey’s weight).

Here, the deficiencies identified by the States are mere “technical flaws” that go to weight not admissibility. Defendant need not demonstrate the “correctness” of Dr. Curtis’s opinion at this time. Thus, the States remain free to level their challenges to Dr. Curtis’s opinion during cross-examination.

b. Bias from the “Here to Help” Program

The States’ second reliability challenge contends that Dr. Curtis’s opinions fail to analyze whether Defendant’s “Here to Help” program biased survey responses. According to the States, many of the physicians and patients who took part in the CAP surveys were participants in Defendant’s “Here to Help” support program that connected patients to doctors, reminded patients to keep appointments, educated and motivated patients, and reminded them to take their medication and refill prescriptions. After the launch of film in September 2010, Reckitt made the “Here to Help” program available only to film patients. In an internal email, James Piano—the lead statistician at CAP on whom Dr. Curtis relied—recognized that the “Here to Help” program skewed physician preferences for film over tablet.⁹ (States Mot., Ex. 24.) Yet, in her deposition, Curtis

⁹ Specifically, Piano commented: “We want to stress that the ratio of HTH [Here to Help] enrolled physicians to non-HTH enrolled physicians was 10 to 3 in this research: this inequality increased branded over generic preference in this sample compared to what would likely occur in the market. In forecasting preference shares this inequality overstates the share preferences for branded!” (States’ Mot., Ex. 24.)

testified that she was “not a hundred percent certain of what the Here to Help program supported,” did not analyze the extent to which the “Here to Help” program might have affected Suboxone sales one way or another, and did not analyze the extent, if any, that the “Here to Help” program might have driven Suboxone preferences one way or another. (Curtis Dep. 264:4–5, 274:4–13.) Dr. Curtis also offered no opinion to assess the impact of Defendant’s marketing activities for Suboxone film or tablets. (Id. 210:7–212:20.)

Contrary to the States’ argument, however, this factor—noted in only one of the surveys reported on by Dr. Curtis—was specifically accounted for in Dr. Curtis’s report. Dr. Curtis explained that this particular study, the Suboxone Preference Shares Among Physicians, was “an online quantitative study designed to provide insight into a number of objectives.” (Curtis Rep. ¶ 58.) In a footnote, Dr. Curtis specifically commented that “[t]he study cautions that high ration of Here-to-Help enrolled physicians may increase branded over generic preference. To eliminate the effects of this preference, I will not comment on the portion of physicians who preferred branded medications over generics. However, this imbalanced preference would not affect results regarding the likes and dislikes of Film.” (Id. n.80.)

Thus, Dr. Curtis specifically considered the impact of the “Here-to-Help” program and opined that it only impacted brand/generic preference, not film/tablet preference. To the extent the States’ expert believes that the “Here-to Help Program” impacted the reliability of the study, it may raise this issue on cross-examination. See Alco Indus., Inc. v. Wachovia Corp., 527 F. Supp. 2d 399 (E.D. Pa. 2007) (“As long as an expert’s scientific testimony rests upon good grounds, based upon what is known, it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors’ scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.”) (quotations omitted).

c. *Safety Messaging*

Finally, the States challenge Dr. Curtis’s opinion that “any safety messaging associated with Film had relatively minor influence on physicians’ and patients’ choice of prescriptions.” (Curtis Rep. ¶ 49.) As a basis for this opinion, Dr. Curtis noted that a common question in the preference studies provided an “array of options for physicians or patients to choose from to gauge both (1) what factors made film more attractive over tablets, and (2) the relative importance of each factor.” (Id. ¶ 50.) Using these questions, Dr. Curtis noted that safety was rarely the leading factor and, in some studies, ranked low as a secondary concern only on physicians’ list of prescribing priorities. (Id. ¶¶ 50–51.) Moreover, Dr. Curtis remarked that studies documented that patients themselves were not influenced by safety claims and ranked safety factors among the lowest factors that prompted their choice of film over tablets. (Id. ¶ 52.) Finally, Dr. Curtis considered comments from physicians and patients on marketing surveys and observed that to the extent patients and physicians valued film’s safety profile, “it was likely for reasons entirely unrelated to marketing” and instead based on experience. (Id. ¶¶ 53–54.)

The States contend that the CAP online questionnaires from which Dr. Curtis derived her opinion “cannot accurately measure the influences of safety concerns because *they simply do not ask about them.*” (States’ Mot. 19–20 (quoting Berndt Rep. ¶ 81) (emphasis in original).) They assert that absent direct questions about the impact, content, or frequency of safety marketing messaging to physicians or patients, Dr. Curtis cannot reliably testify that safety was a secondary concern and not the main driver of film prescribing.

The States’ argument, however, is nothing more than a contention that there was, perhaps, a better way to gauge the impact of safety concerns on physician prescribing decisions. Such a criticism does not undermine the reliability of Dr. Curtis’s methodology or her overall opinion. Indeed, Dr. Curtis discussed surveys that asked participating physicians to rank their preferences for

various film attributes, and those that involved safety concerns repeatedly ranked lower on the list. From those surveys, Dr. Curtis fairly extrapolated a finding that safety concerns did not bear heavily on prescribing decisions. To the extent the States can challenge that opinion, such challenges are more appropriately raised on cross-examination or through rebuttal experts. See AstraZeneca LP v. Tap Pharm. Prods., Inc., 444 F. Supp. 2d 278, 291 (D. Del. 2006) (admitting expert testimony on television survey despite opposing party’s objection that survey did not address certain relevant questions because the objection “can effectively be dealt with on cross-examination, and thus goes to the weight, not the admissibility of the survey.”).

3. Fit

The States’ last challenge to Dr. Curtis’s report asserts that she does not meet the “fit” requirement of Daubert. Specifically, the States argue:

Curtis’s opinions are little more than a character reference for her colleague, and offer no expert testimony as it is traditionally understood—qualitative and quantitative opinions subject to evaluation and proof. Instead, they represent an attempt to end-run inadmissible hearsay into evidence, which is wholly improper. Curtis offers no reliable testimony about the methodology utilized in the studies; her use of them despite her lack of qualifications and sound basis to do so reveal “that there is simply too great an analytical gap between the data and the opinion proffered.” Curtis’ proffered three-page opinion regarding pricing preferences likewise has little or nothing to do with analyzing the survey data at issue. Parroting the survey conclusions without offering further analysis, and acknowledging that even the “opinions” that she offers unique to her reports (generic pricing) are “outside the scope of [her] quantitative surveys,” she offers no actual relevant independent opinions. Thus Curtis’s opinions fail the “fit” test of the Daubert standards for expert testimony.

(States’ Mot. 20–21.)

The States’ argument appears to misunderstand the subject of the “fit” inquiry. As noted above, the issue of fit “is one of relevance and expert evidence which does not relate to an issue in the case is not helpful.” In re TMI Litig., 183 F.3d 613, 670 (3d Cir. 1999). To determine whether

an expert's testimony "fits" the proceedings, this Court asks whether it "will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a); see also UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres, 949 F.3d 825, 835 (3d Cir. 2020).

Dr. Curtis's testimony "fits" these proceedings. The States contend that a substantial portion of film prescriptions resulted from Defendant's false marketing/safety campaign. Dr. Curtis attempts to rebut this theory by opining that physicians and patients chose film for reasons other than safety. Thus, Dr. Curtis's opinions do, in fact, relate to an issue in this case.

For all of the reasons noted above, the States' Daubert Motion will be denied.

V. DEFENDANT'S OMNIBUS MOTION TO PRECLUDE EXPERTS

The next Daubert motion before me is Defendant's Omnibus Motion to Preclude certain of the opinions of the DPPs' experts Nicholas Jewell, Laurence Westreich, Yvonne Tso, Robert Verscharen, Patricia Zettler, and Deborah Jaskot. Given the large range of expert opinions challenged, I address each expert individually.

A. Certain Opinions of Dr. Nicholas Jewell

Defendant first challenges certain portions of the opinions offered by the DPPs' expert Nicholas Jewell. (Def.' Omnibus Daubert Motion ("Def.'s Omnibus Mot."), Ex. 17, Report of Nicholas Jewell ("Jewell Rep.")). According to Defendant, there is extensive evidence, particularly in the form of two "RADARS studies,"¹⁰ indicating that film is less likely than tablets to result in pediatric exposures, or in abuse, misuse, or diversion. Dr. Jewell has been offered by the DPPs to rebut this evidence and opine that neither the available data nor the scientific publications interpreting this data provide a meaningful way to compare film and tablets. Defendant seeks to

¹⁰ RADARS refers to the Researched Abuse, Diversion, and Addiction-Related Surveillance program. (Jewell Rep. at n. 1.) RADARS I looked at the "Root causes, clinical effects, and outcomes of unintentional exposures to buprenorphine by young children." (Id.) RADARS II looked at "Abuse and diversion of buprenorphine sublingual tablets and film." (Id. at n.2.)

exclude two aspects of Dr. Jewell’s opinions: (1) any efforts to compare film and tablets; and (2) opinions on the subjective states of mind of Defendant’s expert witnesses and other scientists.

1. Comparisons Between Film and Tablets

At his deposition, Dr. Jewell was asked, “am I correct that you did not make any affirmative findings regarding whether film is better, worse, or the same as compared to tablets with regard to any metric?” to which he replied, “That was not part of my charge, and I don’t have access to the information to complete that.” (Def.’s Omnibus Mot., Ex. 22, Dep. of Nicholas Jewell (“Jewell Dep.”) 24:24–25:6.) He also testified that he “was not asked to quantify or determine . . . the relative safety of any product” and did not make a determination, one way or the other, as to whether Film is more, less, or equally likely to result in pediatric exposures, as compared to tablet products.” (*Id.* at 22:21–23:9.) Based on this testimony, Defendant now seeks to preclude Dr. Jewell from testifying that film is no safer than tablet products under any metric including pediatric exposures, abuse, and diversion. It also seeks to exclude any opinion from him that film is inferior in any respect to tablet products.

Dr. Jewell’s expert report, however, does not attempt to opine that film is no safer than or inferior to tablet products. Rather, his report seeks only to identify flaws regarding the accuracy and reliability of the RADARs surveys upon which Defendant’s experts rely to opine that film is safer. He summarizes his opinions, in pertinent part, as follows:

10. It is a basic axiom in the field of statistics that the conclusions that can be drawn from a statistical study or analysis are only as reliable as the data from which those conclusions are drawn. Here, as detailed below, the conclusions set forth in the RADARS I and RADARS II articles—including that Suboxone film formulation was ‘safer’ than the table formulation because the film ‘caused’ lower rates of adverse events than tablets—were unreliable from a statistical perspective because the conclusions were based on data that was of poor quality. The data do *not* allow accurate quantification of claimed safety improvements, nor reliable statistical inference regarding whether observed differences in adverse event rates are due to chance

or other factors, as opposed to the formulation used or its packaging. As a result, no reliable conclusions could be drawn from the analyses in the articles, especially concerning an issue as complex and multifaceted as causation. . . .

11. The conclusions in the RADARS articles were also unreliable because the analyses upon which they were based were not designed to draw reliable conclusions about issues such as causation—i.e., whether any observed differences in adverse events between the two formulations were due to, or caused by, differences in the two formulations, such as their packaging, or were due to chance or myriad other potential *confounding* factors. Even if we were to presume that the data used in the RADARS articles were reliable, the RADARS articles could do nothing more than generate a hypothesis about whether the film formulation caused a decline in adverse events. . . . Since no . . . robust studies were performed, no reliable statistical conclusions could be drawn in this case.

12. Similarly, the RADARS I and II articles both fail to establish the “root causes” of any claimed differences in the prevalence or rates of adverse events between the film and tablet formulations. In other words, the articles proving nothing about *what caused* such differences, and specifically whether such differences (if they existed) were due to the formulation used (film or tablet). . . .

(Jewell Rep. ¶¶ 10–12 (emphasis in original) (footnotes omitted).)

Dr. Jewell does not offer any independent scientific comparison of film and tablets. Instead, he relies on his statistical expertise to review and identify defects in the studies relied upon by Defendant’s experts. In turn, he concludes that any opinions reached by Defendant’s experts as to film’s alleged superiority in terms of safety are not entitled to any weight. Such testimony is admissible. See Floorgraphics, Inc. v. News Am. Mktg. In-Store Servs., Inc., 546 F. Supp. 2d 155, 168 (D.N.J. 2008) (admitting expert who was proffered to identify methodological flaws in defendants’ audit).

2. Subjective States of Mind of Defendant’s Witnesses

Defendant also seeks to exclude Dr. Jewell’s reports to the extent they seek to opine on the states of mind of Defendant’s expert witnesses and other scientists. Specifically, in his report, Dr.

Jewell opines that the RADARS studies suffer from a lack of independence from Defendant. (Jewell Rep. ¶ 40.) Dr. Jewell explains that:

13. [T]here was a distinct lack of independence between the scientific investigators who conducted the RADARS analyses and the research sponsors [Reckitt]. Indeed, the RADARS organization, in addition to receiving a \$75,000 from [Reckitt] for the RADARS I manuscript, received a subscription fee of \$650,000 from [Reckitt] for access to data (and hourly rates for any additional services). In addition, Venebio, [Reckitt's] paid consultant, worked closely with RADARS on the articles. These financial interrelationships—and the fact that [Reckitt] put substantial pressure on RADARS to complete work product by tight deadlines in order to achieve [Reckitt's] business objectives—call into question the reliability and objectivity of any conclusions reported in the RADARS articles.

14. Additionally, I have considered certain analyses that [Reckitt] funded, or performed, concerning comparative persistence and compliance rates between users of Suboxone film and Suboxone tablets. These analyses are also problematic in establishing any clear benefit of the Suboxone film formulation over tablets. Comparative data on persistence and compliance based on various forms of pharmacy and insurance claims data are insufficient to assess these concepts reliably, particularly in the absence of adjustment for differential patient costs. Even taken at face value, the results were equivocal with regard to any advantage of one Suboxone formulation over the other.

(Jewell Rep. ¶¶ 13–14.) Dr. Jewell goes on to expand in detail on this alleged bias in the substance of his report. (*Id.* ¶¶ 40–49, 96; Def.'s Omnibus Mot., Ex. 18, Nicholas Jewell Rebuttal Report (“Jewell Reb. Rep.”) ¶¶ 11–12.) Defendant presses that such opinions must be excluded because lack of objectivity is a matter for the trier of fact to resolve and that expert witnesses who may not testify regarding intent, motive or state of mind.

To some extent, Dr. Jewell's opinion is properly focused on whether the surveys at issue were based on the “proper safeguards to insure accuracy and reliability.” Pittsburgh Press Club v. United States, 579 F.2d 751, 755–59 (3d Cir. 1978) (noting that a statistically proper survey requires that: “[1] [a] proper universe must be examined and a representative sample must be chosen; [2] the

persons conducting the surveys must be experts; [3] the data must be properly gathered and accurately reported; [4] the sample design, the questionnaires and the manner of interviewing [must] meet the standards of objective surveying and statistical techniques; [5] the survey must be conducted independently of the attorneys involved in the litigation; and [6] the interviewers . . . ideally should be unaware of the purposes of the survey or litigation”) A substantial portion of Dr. Jewell’s report opines that these specific safeguards were not in place in the RADARS I and RADARS II studies. (See, e.g., Jewell Rep. ¶¶ 40 (“although there are substantial limitations of any analysis of passive reporting data, one common advantage is that there is usually no relationship between the reporting system and the investigators analyzing the data. However, this firewall is not present here . . .”); ¶ 43 (“The relationship between [Reckitt] and Venebio [a separate consulting firm that collaborated with RADARS on Reckitt’s behalf] was not independent in the sense of being at ‘arms-length.’”); *id.* (“In my experience, it is unusual for sponsors to collaborate with researchers in funded academic research in such a way.”). These opinions may be admissible, and Dr. Jewell can explain to the jury, from a statistical perspective, whether Defendant’s involvement in and financing of the study violated these standards of accuracy and reliability.

To the extent, however, that Dr. Jewell seeks to venture beyond such opinions and testify that Defendant’s experts and scientists were impartial or biased, such testimony will be excluded. See Bracco Diagnostics, Inc. v. Amersham Health, Inc., 627 F. Supp. 2d 384, 440 (D.N.J. 2009) (precluding pharmaceutical expert from testifying as to what pharmaceutical company was “trying” to do with its marketing strategy and what it believed was right or wrong); Deutsch v. Novartis Pharms. Corp., 768 F. Supp. 2d 420, 433, 443 (E.D.N.Y. 2011) (stating that the expert “walks a fine line between testifying as to what information is reflected in certain documents, and testifying to what certain individuals at Novartis thought about the information and their motivations for characterizing the information in a particular way”). Opinions regarding state of mind or intent are

not permissible subjects of expert testimony. See In re Tylenol (Acetaminophen) Mktg, Sales Practices, & Prods. Liab. Litig., 181 F. Supp. 3d 278, 295 n.27 (collecting cases holding that expert witnesses are not permitted to testify regarding intent, motive, or state of mind, or evidence by which such state of mind may be inferred).

Examples of such impermissible opinions are scattered throughout Dr. Jewell's report. By way of example, he opines that: "part of RADARS' interest in [Defendant] was presumably to encourage the pharmaceutical company to subscribe to their data resource efforts, thus supplying funds directly to RADARS," "it appears that [Defendant's] interest in RADARS I and II extended beyond simple research goals," and "[Defendant's] representatives were unhappy with the interim report on the RADARS project that was provided by Venebio on August 31, 2012, in part because of the delayed timing of completion of the final version of a RADARS I manuscript." (Jewell Rep. ¶¶ 40, 47, 49; see also id. ¶¶ 41, 44, 45, 46.) For the reasons set forth above, I will grant Defendant's motion to exclude any portion of Dr. Jewell's testimony that comments on state of mind.

B. Certain Opinions of Dr. Laurence Westreich

The next subject of Defendant's Daubert motion is Dr. Laurence Westreich, an associate professor of clinical psychiatry at NY Medical School. Dr. Westreich has peer reviewed more than a hundred articles for medical journals, including analysis of the reliability of the data and methodologies underlying various studies. (Def.'s Omnibus Mot., Ex. 19, Rep. of Laurence Westreich ("Westreich Rep.") ¶¶ 5–18.) He offers four opinions: (1) Defendant did not have substantial scientific evidence to support its safety claims regarding Suboxone tablets as compared to film; (2) Defendant's statements that tablets presented a public risk because they had higher risks of misuse, abuse, diversion, and pediatric exposure than film would have been important to a reasonable Suboxone prescriber; (3) the expectation that tablets would be withdrawn from the market would have been important to a reasonable Suboxone prescriber; and (4) causing physicians

to be suspicious of their patients and/or creating a conflict between physicians' and patients' interests would likely undermine patient treatment and medical outcomes and is therefore inconsistent with Reckitt's statements that it promoted Suboxone film in order to improve the patient experience and public health. (Id. ¶ 29.)

Defendant now argues that three portions of Dr. Westreich's report must be excluded. First, Defendant contends that the portion of the report regarding the "RADARS I" article was not prepared by Dr. Westreich and, therefore, he cannot testify as an expert regarding that article. Second, Defendant challenges Dr. Westreich's opinion that Defendant's marketing influenced other physicians. Finally, Defendant asserts that Dr. Westreich's opinions regarding subjective motivations should be excluded.

1. Opinions Regarding the RADARS I Article

Defendant first seeks to exclude the portion of Dr. Westreich's report that challenges the reliability and validity of the RADARS I study. As noted above, this analysis studied the "Root Causes, Clinical Effects, and Outcomes of Unintentional Exposures to Buprenorphine in Young Children," and was published in the November 2013 volume of Journal of Pediatrics. (Westreich Rep. ¶ 122.) RADARS I concluded that "[e]xposure rates to film formulations are significantly less than to tablet formulations." (Def.'s Omnibus Mot., Ex. 27., at 1.) The DPPs rely on this study to support the fact that the switch to film was for procompetitive reasons. Dr. Westreich opines—over the course of sixteen pages and thirty-seven paragraphs—that multiple aspects of the RADARS study were problematic, thus affecting its reliability. (Westreich Rep. ¶¶ 122–58.)

According to Defendant, Dr. Westreich should be precluded from commenting on the RADARS study because he revealed, at his deposition, that he knew almost nothing about the RADARS I article. Specifically, when asked about it, the following exchange occurred:

Q. Dr. Westreich, are you familiar with Exhibit 9 [RADARS I article]

A. I've seen this article, yes.

Q. Can you tell me—well, have you spent any time analyzing this article?

A. I have looked at it, yes.

Q. And have you come to any conclusions about it?

A. I want to make certain I know which article this is here. I've seen this article, but I haven't done a great deal of analysis of it.

Q. Okay. Have you examined—well how much analysis have you done of exhibit 9?

A. Not very much.

(Def.'s Omnibus Mot., Ex. 21, 201:12–202:2.) Defendant points out that during the course of this testimony, Dr. Westreich took multiple pauses and spent extensive amounts of time flipping through both the article and his report. (Def.'s Omnibus Mot., Ex. 86, Video Clip of Westreich Dep.) Indeed, Defendant notes that Dr. Westreich could not answer a simple question about “what data sources are used” in the article without taking additional time to look through the article. (Westreich Dep. 202:3–25.) From this, Defendant surmises that “[g]iven the extraordinary level of detail of [Dr. Westreich's] report [on RADARS I], Dr. Westreich's unfamiliarity with RADARS I at the deposition is utterly inconsistent with the notion that this portion of his report was ‘prepared . . . by the witness’ within the meaning of Rule 26(a)(2)(B).” (Def.'s Omnibus Mot. 9.) Defendant asserts that because Dr. Westreich clearly did not author this portion of the report, Federal Rule of Civil Procedure 26(a)(2) requires that it be excluded.

In response, the DPPs contend that various copies of the RADARS I article had been produced in varying formats throughout discovery, none of which say “RADARS I” in the title. Therefore, when first shown the article in his deposition, Dr. Westreich initially did not recognize it and needed to refresh his recollection. The parties took a break in the deposition, after which Dr. Westreich made a correction in his testimony, as follows:

A. I failed to identify one of the articles that I did look at in some depth which is the root cause, clinical facts and outcomes of

unintentional exposure to buprenorphine in children. In fact, I wrote several pages in my report.

Q. Was the article unfamiliar to you when you saw it in this deposition?

A. Actually, the face of it was because it looked different as I was reading it. There's two Lavonas articles [RADARS I and RADARS II], so it was unfamiliar to me.

Q. Are you less familiar with the other Lavonas article?

A. Am I less familiar with the other one?

Q. Yes.

A. I don't believe so, no.

Q. How did it come to your attention that you had made an error on the record?

A. As you were asking me about it, it seemed very familiar, but since this one looked different, I wasn't able to identify it, and I realized that as we were talking.

Q. When we were off the record, did you have any conversation with anyone about this error in the record.

[Objection regarding attorney-client privilege]

(Westreich Dep. 212:10–213:23.) Plaintiff now argues that Dr. Westreich's "brief lapse of recall during deposition," particularly in the face of his sworn testimony that he recognized the RADARS I study and had discussed it in his report, does not warrant exclusion of this part of his report.

Federal Rule of Civil Procedure 26 requires that expert reports be "prepared and signed by the witness. . . ." Fed. R. Civ. P. 26(a)(2)(B). Although the Advisory Committee Notes to Rule 26 state that the Rule "does not preclude counsel from providing assistance to experts in preparing the reports," Fed. R. Civ. P. 26 advisory committee's notes (1993), Rule 26(a)(2)(B) "does not contemplate blanket adoption of reports prepared by counsel or others. . . ." 6 James Wm. Moore et al., Moore's Federal Practice ¶ 26.23[4] (3d ed. 2000).

Dr. Westreich's report is 123-pages long and his reference to the RADARS study is extensive. Dr. Westreich's initial confusion certainly does not establish, under Daubert standards,

that he did not prepare that portion of his report.¹¹ Dr. Westreich’s deposition reflects that he was originally unclear about the nature of the RADARS I report, but, after having an opportunity to review that report, he was able to quickly and directly answer multiple questions in detail about the study. (Westreich Dep. 202:19–211:17.) Immediately after questioning on that report, counsel took a break in the deposition. When the parties returned from the break, Dr. Westreich corrected his testimony—on the record and under oath—and stated that he had in fact reviewed the study in detail.

As noted by one district court faced with a similar allegation that an expert did not prepare his own report:

Litigation continually proceeds with assumptions that any witness, expert or otherwise, may have made different and sometimes inconsistent statements about relevant matters. The inconsistencies often relate to inconsequential details. They may also relate, of course, to material matters. Inconsistencies occur for various reasons. Memories dim. People make mistakes in recall. They sometimes speak carelessly, impulsively, and with little thought or discretion about their choice of language. They choose words which inadequately or inaccurately express what they mean to say. Trial courts often instruct juries, in weighing the credibility of witnesses, to consider whether their inconsistent statements relate to matters of

¹¹ I do not find Defendant’s cited cases persuasive as each case involved either (a) an expert who admitted that he/she did not prepare certain portions of the report or (b) there was clear and convincing evidence that the expert did not prepare the report. I have neither scenario before me. See, e.g., Numatics v. Balluff, 66 F. Supp. 3d 934, 941 (E.D. Mich. 2014) (excluding expert report where expert conceded at deposition that defendant’s counsel wrote the expert report and the expert reviewed the draft of the 64-page report for only a couple of hours before signing it); DataQuill Ltd. v. Handspring, Inc., No. 01-4635, 2003 WL 737785, at *4 (N.D. Ill. Feb. 28, 2003) (excluding expert testimony where expert admitted that plaintiff’s counsel actually typed his report, large quantities of plaintiff’s interrogatory responses appeared verbatim in the expert report, and expert did not even follow a proper infringement analysis); Play Visions, Inc v. Dollar Tree Stores, Inc., No. 09-1769, 2011 WL 2292326, at *9 (W.D. Wash. June 8, 2011) (excluding expert report where expert admitted at deposition that counsel had just asked questions of the expert and filled in the answers on the report and that the expert did not see the final report until after it was circulated to the defendants; expert then submitted a “change” sheet after reviewing his deposition testimony which had “wholesale reversals of his testimony under oath” without any explanation); Stein v. Foamex Int’l, Inc., No. 00-2356, 2001 WL 936566, at *5 (E.D. Pa. Aug. 15, 2001) (excluding expert affidavit where expert never claimed to have played any substantial role in its preparation, other than signing it, and party offered no evidence that expert prepared affidavit in any meaningful way).

material importance or of lesser consequence and whether they reflect either honest mistake on the one hand or an intent to deceive on the other.

The court generally would not disqualify a witness upon grounds he has changed his testimony after talking with an attorney. It would instead give opposing counsel the opportunity to cross-examine the witness. Effective cross-examination serves to expose inconsistencies of importance. It may also develop the extent to which a witness has been influenced by counsel to make changes in what he says. Similarly here. That a report of the expert has been revised, after a conference with the attorney, should not lead the court to hastily strike the designation of the witness. Defendant should instead find his recourse by cross-examination of the expert.

Marek v. Moore, 171 F.R.D. 298, 301–02 (D. Kan. 1997).

At trial, Defendant will be given significant leeway to further probe this issue before the jury and, if justified, re-raise its motion to exclude this portion of Dr. Westreich’s testimony.

2. Opinions Regarding Influence of Defendant’s Marketing on Physicians

Defendant next seeks to exclude the section of Dr. Westreich’s report stating that “Reckitt’s Film-superiority statements and withdrawal statements would have been important to the reasonable Suboxone prescriber.” (Westreich Rep. § V.) In this section, Dr. Westreich opines that “[b]ased on [his] experience training other doctors, working in hospitals and clinics, serving on panels and medical associations, and interacting with other doctors,” the “average, reasonable” physician would be impacted and influenced by Reckitt’s claims about the tablets’ dangers, would have maintained an anti-tablet bias after generic tablets became available, and would have factored information about impending tablet withdrawal into their treatment decisions. (Id. ¶¶ 235–70.)

Defendant contends that such opinions regarding what other doctors deem material must be based on something more reliable than simply the expert’s own experience as a doctor. Defendant asserts that a naked reference to “experience” is not a reliable methodology; rather the expert must explain how that experience leads to the conclusion reached. According to Defendant, Dr.

Westreich’s report never explains how his experience leads to his conclusions and, as such, any statement as to what other physicians with certain information would think is purely speculative and not based on scientific knowledge.

The DPPs respond that Dr. Westreich’s opinions are appropriately based on his decades of experience training medical students to treat addicted patients, as a psychiatrist making treatment decisions for patients, and as a peer reviewer of scholarly articles. The DPPs point out that Dr. Westreich also reviewed sufficient evidence, including Reckitt field reports and internal analyses about how doctors in fact reacted to the promotional statements, including a December 2010 Reckitt survey of 300 doctors about why physicians prefer Suboxone film over tablet.

Where traditional Daubert reliability factors are not workable, the Supreme Court has noted that the “relevant reliability inquiry concerns may focus upon personal knowledge or experience.” Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 150 (1999). Indeed, expert testimony may be based on “experience alone—or experience in conjunction with other knowledge, skill, training or education.” Fed. R. Evid. 702, advisory committee’s note 2000. “In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony.” Id.; see Kumho Tire Co., 526 U.S. at 156 (“[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.”).

With respect to the particular testimony at issue here, the Third Circuit has recognized that a doctor’s experience alone renders him a reliable witness to testify about a reasonable standard of care or what a reasonable physician would do. Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 405–07 (3d Cir. 2003) (reversing exclusion of expert testimony about standard of care during pre-treatment for angioplasty). Consistent with that principle, numerous cases have held that a doctor may, based on his or her experience, “testify about what a reasonable doctor *should* know” or “how a reasonable doctor would interpret [a] safety warning.” Bartlett v. Mut. Pharm. Co., Inc.,

742 F. Supp. 2d 182, 196 (D.N.H. 2010) (emphasis in original); see also In re Bard IVC Filters Prods. Liab. Litig., No. MDL 15-2641, 2018 WL 495188, at *4 (D. Ariz. Jan. 22, 2018) (“The Court finds that Dr. Muehrcke has sufficient knowledge and experience to offer his opinion as to the information reasonable physicians expect to receive from IVC manufacturers, and whether physicians who implant IVC filters reasonably expect a properly implanted filter to tilt, perforate the IVC, or fracture and migrate to neighboring organs.”); Deutsch v. Novartis Pharms. Corp., 768 F. Supp. 2d 420, 440, 443 (E.D.N.Y. 2011) (finding that doctor could opine, based on professional experience alone, whether warning labels on drug were false or misleading from the perspective of a reasonable prescribing physician and whether certain information contained in drug company’s internal documents regarding risks of drugs would have been useful to doctors in making prescribing decisions).

However, “most courts have prohibited experts from testifying ‘about what all doctors generally consider in making prescription decisions’ or about ‘what doctors generally think,’ unless the testimony is based on something more reliable than simply the expert’s own experience as a doctor.” Bartlett, 742 F. Supp. 2d at 196 (quoting In re Diet Drugs Prods. Liab. Litig., No. MDL 1203, 2000 WL 876900, at *11–12 (June 20, 2000)) (additional citations omitted); see also In re Loestrin 24 Fe Antitrust Litig., 433 F. Supp. 3d 274, 302–03 (D.R.I. 2019) (holding that doctor may not testify as to what all physicians do or consider in making prescribing decisions, but may testify as to his own prescribing decision-making process and knowledge, as well as that of his colleagues or other doctors with whom he has personal experience); In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531, 557 (S.D.N.Y. 2004) (“Unlike opining about what physicians in general expect to see on a label, [expert]’s surmising as to what physicians would do with different information is purely speculative and not based on scientific knowledge.”); In re Seroquel Prods. Liab. Litig., No. MDL 06-1769, 2009 WL 3806436, at *8 (M.D. Fla. July 20, 2009) (holding that expert doctors may

express opinions regarding accuracy and adequacy of drug label without reference “to the asserted perceptions of other doctors” or whether doctors generally understand the contents of the label).

Here, Dr. Westreich’s report tiptoes the line between properly opining how Defendant’s marketing materials affected both his prescribing decisions and those of physicians with which he has had contact, and improperly speculating what impact those marketing materials had on the prescribing decisions of all physicians. To clarify where that line follows, I hold that Dr. Westreich may testify that Reckitt’s statements regarding safety risks of tablets versus film would be material to him and, in his experience, the reasonable Suboxone prescriber. He may not, however, testify that “when Reckitt Benckiser representatives reported that Suboxone Tablets were prone to inadvertent pediatric exposure, misuse, and diversion, doctors would of course assume that the generic buprenorphine/naloxone tablets would have the exact same set of side effects and adverse effects” and would “remain reluctant to prescribe buprenorphine/naloxone tablets of any sort.” (Westreich Rep. ¶ 255.) Similarly, while he may opine about why he would not prescribe a medication that would soon be withdrawn from the market, he cannot opine that “[i]f a particular medication or preparation will soon be withdrawn from the market, most doctors would stop prescribing that medication[] to new patients and would start transferring their patients to other medications or preparations.”¹² (*Id.* ¶ 268.) Thus, to the extent Dr. Westreich limits his testimony to what factors he considers in making prescribing decisions, it will be admissible.¹³ To the extent

¹² The DPPs argue that Dr. Westreich has reviewed internal Reckitt documents, including the survey of how 300 doctors reacted to Reckitt’s promotional statements, and as such, he is qualified to render opinions about physicians in general. I disagree. Dr. Westreich is a physician, not a statistician who has conducted extensive surveys about which he can testify.

¹³ Defendant also argues that Dr. Westreich’s report is undermined by his own deposition testimony where he states that when teaching medical students or young doctors how to evaluate claims that drug manufacturers make about their products, he tells them to rely on research that has a solid scientific basis as opposed to marketing materials from the drug companies unless there is substantiation. (Westreich Dep. 138:16–140:21.) Any such contradiction between Dr. Westreich’s opinion as to prescribing practices in his experience and Dr. Westreich’s deposition testimony

he seeks to speculate what other physicians generally did or would do, such testimony will be excluded.

3. Opinions Regarding Subjective Motivations

Defendant's final challenge to Dr. Westreich alleges that his opinions regarding subjective motivations should be excluded. Specifically, like Dr. Jewell, Dr. Westreich opines that researchers were biased due to their interactions with Reckitt. (Westreich Rep. ¶¶ 144–58, 189–92, 232.) Dr. Westreich also opines that Defendant's expert, Dr. Murrelle, "has a self-interest and motivation to not find any flaws with reports that his company [Venebio] . . . aided Reckitt in developing." (Def.'s Omnibus Mot., Ex. 20, Westreich Rebuttal Report ("Westreich Reb. Rep.") ¶ 32.)

As noted above, Dr. Westreich has peer reviewed more than a hundred articles for medical journals, including analysis of the reliability of the data and methodologies underlying various studies. Thus, like Dr. Jewell, Dr. Westreich may permissibly testify, based on his experience in peer review, regarding whether the circumstances under which reports or other studies were prepared violated well-established safeguards on independent, accurate, and reliable studies.¹⁴

But Dr. Westreich also ventures into the impermissible territory of commenting on state of mind. By way of example, he states:

- "The documents indicate to me that Reckitt made clear to Venebio that Reckitt was 'the customer' and that the project's

regarding such practices is not the basis for exclusion of his report, but rather is properly raised on cross-examination.

¹⁴ (See, e.g., Westreich Rep. ¶ 103 ("Medical research that is solely funded by pharmaceutical companies often draws questions of reliability. Studies that are entirely paid for by pharmaceutical companies tend to have results that favor the industry."); ¶ 109 (discussing different types of bias that can occur in studies); ¶ 147 ("From the early planning stages, Reckitt had substantial involvement in creating the objectives, design, execution, and ultimate wording of the pediatric exposure analysis."); ¶ 155 ("documents extrinsic to the paper also show that it was finalized under extraordinary time pressures, which may also have contributed to data inaccuracies."); ¶ 189 ("as with the Pediatric Exposure Analysis, Reckitt Benckiser had substantial input into the design of the Lavonas Abuse and Diversion study."))

methodology and design should be tailored to Reckitt’s specific ‘business goals.’” (Id. ¶ 148.)

- “Furthermore, the documents indicate that, from the outset, the parties understood that Venebio would allow Reckitt to influence the paper’s wording.” (Id. ¶ 150.)
- “In my opinion, Reckitt’s involvement in setting the project objectives, designing and implementing the protocols, and drafting the manuscript calls into question Venebio’s statement in the published paper that ‘The authors had full control of all aspects of study design, data collection, data analysis and management, and the decision to publish. Reckitt Benckiser Pharmaceuticals was able to review the manuscript only for proprietary information.’” (Id. ¶ 154.)
- “In my opinion, the references to ‘getting the budgeting secured’ and ‘business usefulness’ telegraph Reckitt Benckiser’s desire to get results which would advance its business interests, or it would not fund the project.” (Id. ¶ 191.)
- “Dr. Murrelle’s bias in assessing his own studies also cannot be ignored. Since he is employed by the very entity whose research he is defending, and he produced the research himself, bias in favor of that research is inevitable. He has a self-interest and motivation to not find any flaws with reports that his company, Venebio, aided Reckitt in developing.” (Westreich Reb. Rep. ¶ 32.)

Similar to my finding regarding Dr. Jewell, Dr. Westreich may not comment on state of mind or the credibility of Defendant’s researchers and expert witnesses. See In re Seroquel, 2009 WL 3806436, at *8 (“[I]t is one thing for an expert to testify . . . to explain and compare information in Seroquel marketing materials to other evidence—and quite another matter for an expert witness to render an opinion concerning what a drug company intended or sought to achieve through the use of those marketing materials. The latter are proper subjects for closing argument, not expert testimony.”). Accordingly, I will grant Defendant’s motion to exclude any portion of Dr. Westreich’s testimony that comments on subjective motivations.

C. Certain Opinions of Yvonne Tso

The DPPs have identified Yvonne Tso as an expert in managed care with different types of healthcare and healthcare-related experiences acquired over the course of thirty years. (Def.’s Omnibus Mot., Ex. 14, Report of Yvonne Tso (“Tso Rep.”) ¶ 1.) Ms. Tso offers several opinions:

1. Reckitt’s tablet withdrawal statements, public health risk statements, and pricing tactics would have been relevant to the typical, reasonable Managed Care Organization (“MCO”) decisionmaker’s decisions regarding film and tablet placement and likely resulted in decisions that gave film favorable formulary placement and blocked or restricted coverage for Suboxone tablets;
2. Reckitt’s statements about tablet’s higher risks of misuse, abuse, diversion, and pediatric exposure would cause a typical, reasonable MCO decisionmaker to adjust the formula to disfavor the purportedly less safe product (tablets) and favor the utilization of the purportedly safer product (film);
3. Reckitt’s pattern of raising tablet prices during the pre-generic period, combined with eliminating tablet rebates, would place enormous economic pressure on the typical, reasonable MCO decisionmaker to make formulary adjustments to drive patients and doctors to film;
4. Reckitt’s combined tactics from 2009 through 2012 would have been significant and material to a typical, reasonable MCO decisionmaker’s formulary decisions to favor film and disfavor tablets, which in turn made tablets economically inaccessible to patients and imposed costly administrative burdens on doctors who prescribed tablets; and
5. Reckitt’s conduct had the effect of entrenching film in the market, making it difficult for many MCOs to disfavor film on formularies after generic tablets entered.

(Tso Rep. ¶¶ 17–23.)

Defendant raises two challenges to Ms. Tso’s opinions. First, it contends that Ms. Tso’s bald invocation of her “experience” is not a basis for her opinions and, absent any testimony of her actual experiences, her methodology is unreliable. Second, it asserts that Ms. Tso ignored contrary evidence, thus rendering her opinions impermissibly speculative.

1. Invocation of “Experience” as Methodology

Defendant first challenges Ms. Tso’s opinions about the materiality and causal effect of Defendant’s alleged withdrawal and safety statements because such opinions are based solely on her “experience.” According to Defendant, Ms. Tso did not conduct any type of survey to ascertain the impact of the communications at issue and has never asked anyone at a managed care organization (“MCO”), health plan, or pharmacy benefit manager (“PBM”) about how they reacted to the alleged statements at issue. Defendants note that, at her deposition, Ms. Tso did not explain how her experience led to the conclusion reached, could not recall any of her actual experiences in determining formulary placements or other directly applicable experiences, could not remember examples of any analogous situations, and testified contrary to her own experience regarding safety claims.

While these alleged deficiencies may provide useful cross-examination, this challenge is an insufficient basis on which to exclude Ms. Tso’s testimony. “The text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience. “In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony.” Fed. R. Evid. 702, Advisory Committee’s Note (2000). “If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.” Id. Repeatedly, courts have permitted experts to rely solely on their experience to opine on how a reasonable individual within the same industry would react. See, e.g., In re Yasmin and YAZ (Drospirenone) Mktg., Sales Practices and Prods. Liab. Litig., MDL 09-2100, 2011 WL 6302287, at *13 (S.D. Ill. Dec. 16, 2011) (“As the former Commissioner of the FDA, with unquestioned knowledge of the regulatory scheme and requirements, Dr. Kessler may testify about what a reasonable FDA official would have done with information about VTE adverse events.”);

Krommenhock v. Post Foods, LLC, 334 F.R.D. 552, 579 (N.D. Cal. 2020) (declining to exclude advertising expert opinion, based on experience alone, about the impact that advertising has on consumer perceptions regarding the health and wellness benefits of consumer products generally and consumer behavior and decision-making as it relates to labeling claims on cereal packaging, even though expert did not conduct an focus groups or consumer testing); Veleron Holding, B.V. v. Morgan Stanley, 117 F. Supp. 3d 404, 445 (S.D.N.Y. 2015) (expert on banking industry standards “had worked in five of the preeminent firms in a highly competitive industry” and had “become acquainted with each firm’s code of conduct during his years of service,” so “the fact that he did not conduct a ‘survey’ before reaching his conclusion, or did not obtain a copy of every other bank’s internal policies, is at best an avenue for cross-examination, rather than a disqualification from testifying.”).

I find that Ms. Tso’s testimony is permissible given the complex nature of formulary decisions by managed health care organizations. Ms. Tso may offer such opinions based on her experience as a retail and hospital pharmacist, in healthcare financing, and within managed care organizations where she was involved with all aspects of pharmaceutical benefit administration, formulary, and utilization decisions. (Tso Rep. ¶¶ 1–10.) Although she did not conduct any particular surveys, her experience alone qualifies her to opine on how Defendant’s safety messages, tablet withdrawal statements, and practice of raising tablet prices would have factored into a reasonable, objective MCO decisionmaker’s formulary adjustments. Ms. Tso also bolstered her opinion by citing to documentary and testimonial evidence that MCOs in fact made formulary decisions because of Defendant’s withdrawal statements and claims that film was safer, and she explained the precise reasons how and why Defendant’s actions impacted formulary and prescribing decisions. (Tso Rep. ¶¶ 38, 42, 53, 72, 74, 104, 115, 138, 150–51.)

Regarding Defendant's challenges to Ms. Tso's inability during her deposition to testify (a) about her actual experiences in determining formulary placement for these particular products, (b) in understanding what withdrawal or safety concerns were raised in her presence, or (c) even to identify examples of analogous situations, these are insufficient reasons for exclusion. Ms. Tso was able to identify several companies for she was involved in a formulary decision involving buprenorphine products. (Def.'s Omnibus Mot, Ex. 54, Dep. of Yvonne Tso ("Tso Dep.") 46:10–47:7.) She went on to state that "I don't think I can name all of them *because there are so many*." (*Id.* at 47:12–13 (emphasis added).) Although Defendant asserts that Ms. Tso had no recollection of her actual experiences in determining formulary placement for these products, my reading of her testimony differs. She explained that her experience with respect to buprenorphine drugs was so vast and varied, much of it occurring years earlier, she simply could not recall the particulars for each of the discussions. (*Id.* at 49:7–56:24.) Any memory lapses as to specific conversations in years past are simply a basis for cross-examination.

I also find no merit to Defendant's allegation that Ms. Tso's opinion on the safety claims is belied by her testimony about her actual experiences. As noted above, Ms. Tso opined that Defendant's safety statements about the tablet would cause a typical, reasonable MCO decisionmaker to adjust the formula to disfavor the tablet. At her deposition, however, Ms. Tso testified that MCOs retain Pharmacy and Therapeutics committees to evaluate marketing claims by pharmaceutical companies and determine if they are corroborated by scientific studies. (Tso Dep. 72:3–73:9.) While such testimony perhaps affects the weight of her opinion, it does not, under Daubert standards affect its reliability.

2. Failure to Consider Contrary Evidence

Defendant's second challenge to Ms. Tso's testimony contends that she simply ignored contrary evidence regarding both alleged tablet-withdrawal and safety-claim statements. With

respect to Defendant's alleged tablet-withdrawal communications, Defendant alleges that Ms. Tso failed to identify a single instance where a "withdrawal statement" caused any MCO to remove Suboxone tablets from a formulary. With respect to Defendant's alleged safety claims regarding tablets, Defendant argues that Ms. Tso (a) failed to explain why these communications did not deter commercial insurers from near-universal coverage of generic tablets, and (b) could only identify one MCO as having made a formulary decision based even in part on safety considerations.

Defendant's argument "reflects a fundamental confusion about the role of the court as a gatekeeper, under Daubert, to determine the admissibility of evidence, and the role of the jury, as a fact finder, to determine the weight to be accorded to admitted evidence." ID Security Canada, Inc. v. Checkpoint Systems, Inc., 249 F. Supp. 2d 622, 691–93 (E.D. Pa. 2003). As has become a mantra throughout this opinion, the Supreme Court has admonished that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 596 (1993); see also In re Mirena IUD Prods. Liab. Litig., 169 F. Supp. 3d 396, 427 (S.D.N.Y. 2016) ("To whatever extent Defendants' public or internal statements conflict with its experts' opinions or its litigation positions in these cases, that will be a problem for Defendants that Plaintiffs may exploit via cross-examination and argument. But Defendants' experts' failure to confront alleged conflicting statements . . . does not warrant exclusion under Daubert.").

As Ms. Tso's failure to address potential factual inconsistencies does not bear on the reliability of her testimony and may be tested through cross-examination, I will deny Defendant's Daubert motion on this ground.

D. Certain Opinions of Robert Verscharen

Defendant's omnibus Daubert Motion next challenges identified DPP expert Robert Verscharen. Mr. Verscharen—an individual with forty years' experience in the pharmaceutical industry—was retained by the DPPs as an expert on the business of pharmacy purchasing and dispensing of prescription drugs at the retail level. (Def.'s Omnibus Mot., Ex. 15, Robert Verscharen Report ("Verscharen Rep.") ¶ 1.) His report (1) describes the history of generic prescription drugs in the marketplace, with a focus on the rise of the substitution of AB-rated generic drugs for branded drugs from the perspective of the retail pharmacy level of distribution; (2) opines that the AB-rating is the linchpin of the savings to drug purchasers at all levels of the distribution chain; and (3) explains that therapeutic substitution is not as efficient or effective as AB-rated substitution in delivering cost savings to purchasers, dispensers and consumers, and why a therapeutic substitution program to move prescriptions from Suboxone film to generic tablets, if it had been attempted, would have been inefficient and unsuccessful.¹⁵ (Id. ¶ 9.)

Defendants move to preclude these opinions on two grounds. First, to the extent that Mr. Verscharen claims that competition between film and generic tablets was hindered at the pharmacy counter due to the lack of automatic substitution, Defendant contends that the DPPs withheld evidence on this subject during discovery and may not now proffer an expert on this subject.

¹⁵ Mr. Verscharen succinctly explained the difference between AB-rated substitution and therapeutic substitution. When a prescription has an AB-rated generic, the pharmacist has the authority, and in most states, the responsibility, to use a generic whenever available. If no AB-rated generic is available, then the pharmacist must fill the prescription as written.

In some limited instances, however, a pharmacist may attempt to do a therapeutic substitution. This may occur when a pharmacist receives a prescription for a brand name drug that does not have an AB-rated generic associated with it, but there may be another drug available with a similar therapeutic result that might provide benefits (economic or clinical) to the patient, as well as economic benefits to the pharmacy. This other drug would have a different chemical, dosage strength or dosage form, and would be dispensed in place of the originally prescribed product. For therapeutic substitution to occur, however, the pharmacist must call the doctor and have the prescription changed. (Verscharen Rep. ¶¶ 48–50.)

Second, Defendant posits that Mr. Verscharen’s opinion that “therapeutic substitution programs in general are difficult, inefficient, and rarely successful” lacks both an adequate basis and a reliable methodology.

1. Exclusion Based on Failure to Produce Evidence

Defendant first maintains that, during discovery, it requested that DPP class representative Meijer, Inc.—which runs a chain of pharmacies—produce “[a]ll documents relating to the switching between or among Buprenorphine Products” and documents relating to sales and communications regarding sales of these products. (ECF No. 178-1, Req. Nos. 2, 12, 14.) Presumably, Defendant requested this discovery because it bore on whether there was any antitrust impact resulting from Defendant’s alleged actions. Meijer objected to such production, arguing that although documents relating to its purchases were relevant, “downstream discovery” relating to sales or interactions with consumers was irrelevant. In response to Defendant’s motion to compel documents, Meijer produced a spreadsheet of invoice-level sales data going back seven years, including the date the prescription was filled, a description of the product dispensed, the manufacturer, the dispensed product identifying information, the co-pay information, the insurer or third-party payment information, any dispensing fee collected, any coupon used, the insurer or other carrier used, and an individual patient ID number to track any drug changes or changes in insurance over time. In response to further motion practice regarding this discovery, I found that Meijer’s spreadsheet production satisfied their burden. (ECF No. 286-1). When Defendant sought additional information about downstream competition through a Rule 30(b)(6) notice issued to Meijer, Meijer refused to produce a witness on this subject. Defendant now speculates that “[i]t is highly likely that Meijer had responsive documents, as even Mr. Verscharen admits that pharmacies take vigorous efforts to inform consumers of the availability of generic products.” It contends that the DPPs cannot offer

an expert on a subject regarding which it withheld documents and testimony. (Def.'s Omnibus Mot. 22.)

Reviewing the document requests referenced by Defendant, I see no request directed specifically towards therapeutic substitution and whether it was effective in the absence of automatic substitution between AB-rated products. Moreover, it is not clear that Meijer had any such responsive documents. Indeed, Meijer's own Rule 30(b)(6) witness testified that Meijer had no policies directing substitution of a cheaper generic if the products were not AB rated:

Q. When a pharmacist is presented with a prescription, what should he do according to Meijer's policies?

A. Fill the prescriptions written.

Q. If the prescription is written using the brand name of a drug for which there are substitutes available, what does Meijer's policy direct the pharmacist to do?

...

A. . . . If a generic is available, then it would be our pharmacists, within their rights to substitute a generic alternative to help save the patient money.

Q. Does Meijer have a policy regarding whether the pharmacist should do that?

A. No.

Q. Is the goal of Meijer's substitution to save the customer money?

A. Ultimately we are acting on the customer's behalf, and saving them money is very important, yes.

Q. So if a generic substitute is not cheaper, does Meijer have a policy whether or not the pharmacist should substitute in that circumstance?

A. No.

(Meijer 30(b)(6) Dep. 21:25–23:13.) Given such testimony, it is not clear what additional documents Meijer could have produced that Defendant would have used to rebut Mr. Verscharen's opinion that pharmacists can steer patients towards generic products.

As Defendant has not proven that DPPs failed to produce evidence bearing on the substance of Mr. Verscharen's report, I decline to grant Defendant's Motion on this ground. Should Mr.

Verscharen testify at trial on subject areas which Defendant believes were the subject of valid but unresponded-to discovery requests, Defendant may raise a relevant objection at that time.

2. Opinions on the Difficult Nature of Therapeutic Substitution Programs

Defendant also objects on the grounds of qualification and reliability with respect to Mr. Verscharen's opinion that "[t]herapeutic substitution programs in general are difficult, inefficient, and rarely successful." (Verscharen Rep. § B.) Mr. Verscharen asserts that therapeutic substitution seldom occurs because of "the economics of pharmacy," which considers the difficulties and costs inherent in therapeutic substitution. Specifically, for therapeutic substitution to occur, the patient must be asked if they want the lower-cost generic, the pharmacist has to check insurance coverage, the pharmacist has to discuss costs and benefits with the patient, the physician must be contacted about the substitution and will often not be reached immediately, the pharmacist must document the revised prescription, and ultimately the new prescription must be transmitted to the store. (*Id.* ¶¶ 50–52.) Mr. Verscharen concludes that "the cost to the pharmacy of filling a prescription through a therapeutic substitution, under the best of circumstances (a centralized facility for such functions), is over \$8.00 prescription. This compares with no additional cost for filling a prescription through AB-rated substitution." (*Id.* ¶ 56.)

While such testimony in itself is admissible, the problem arises with Mr. Verscharen's subsequent opinion that a therapeutic substitution program to move prescriptions from Suboxone film to generic Suboxone tablets, if it had been attempted, would have been inefficient and unsuccessful. This is because his methodology in reaching this opinion relies on a single example of problems inherent in the therapeutic substitution program relating to the drug TriCor. He explains that, in 1998, Abbott Laboratories entered the market with the drug TriCor in capsule form, which did not have patent protection. (*Id.* ¶ 59.) In anticipation of threatened generic competition, Abbott developed a tablet form of Tricor which would be bioequivalent to, but not AB-rated with, the prior

form, and it stopped selling its Tricor capsules. (Id. ¶ 60.) Thus, by the time generic competitor Teva obtained FDA approval for its generic capsules, the majority of Tricor prescriptions were for the tablets. (Id.) Because the capsules were not AB-rated to the tablets, Teva could not get automatic substitution at the pharmacy counter. (Id. ¶ 61.) Therefore, Teva decided to launch its capsule product as a branded generic drug, under the name Lofibra, and designed a therapeutic substitution program that encouraged pharmacies to contact physicians and convince them to change their Tricor prescriptions to the chemical name (fenofibrate) and in the capsule form. (Id. ¶ 62.) Teva paid for the program, but ended up cancelling it in less than six months because of a lack of pharmacy participation and/or conversions. (Id.) In addition, Teva faced competition from other generic companies who developed generic capsules that were AB-rated to the Lofibra tablets. (Id. ¶ 63.)

From this scenario, Mr. Verscharen opines that Suboxone presented similar problems with regards to the potential success of a therapeutic substitution program. (Id. ¶ 65.) He notes that tablets were not AB-rated to Suboxone film, so a therapeutic substitution program seeking to switch Suboxone film prescriptions to generic tablets “was likely to fail,” just as the program seeking to switch Tricor tablet prescriptions to capsules failed. (Id.) He explains that therapeutic substitution of generic tablets for Suboxone film would have been particularly difficult if, as Plaintiffs allege, there was a three-plus year campaign by Defendant to aggressively disparage the safety of tablets. (Id. ¶ 69.) Mr. Verscharen goes on to assert that “even in the unlikely event that a therapeutic substitution program involving Suboxone was attempted, it is a virtual certainty that the program would result in far less savings to purchasers (including patients) than automatic AB-rated generics would have produced if Defendants had not engaged in the challenged scheme.” (Id. ¶ 70.) Finally, he opines that if therapeutic substitution were to become the norm in the pharmaceutical industry, it

would result in lower generic substitution and higher prices to consumers because of the cost to the pharmacy of engaging in the therapeutic substitution process.

I do not find that Mr. Verscharen's methodology fits the facts of this case. As set forth above, to determine whether an expert's testimony "fits" the proceedings, this Court asks whether it "will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Had Mr. Verscharen applied his experience in the pharmaceutical industry to the particular facts here—*i.e.*, whether a generic manufacturer of buprenorphine naloxone tablets could have successfully launched a therapeutic substitution program for prescriptions written for branded film—his opinion may have helped the trier of fact. However, Mr. Verscharen premised his opinion on only general pharmaceutical experience and a single example from more than a decade earlier when a different generic company's effort to launch a therapeutic substitution for a different drug under different circumstances was unsuccessful. Such an example, while perhaps identifying pitfalls and obstacles in that program, does not easily translate to the same pitfalls and obstacles in a therapeutic substitution program here. Mr. Verscharen had no idea of what Plaintiff Meijer did to switch prescriptions between film and generic buprenorphine naloxone tablets and made no effort to understand Meijer's opinions and experience. (Def.'s Omnibus Mot., Ex. 43, Dep. of Robert Verscharen ("Verscharen Dep.") 113:2–23.) He also did not (a) address whether generic manufacturers thought that pharmacies could effectively help switch prescriptions to generics, (b) review any documents from the record regarding how generic manufacturers understood the competition between their products and the film product, or (c) look to see whether the generic manufacturers here tried to advertise their products. (Id. at 116:20–117:11.) Finally, Mr. Verscharen admitted that he had done no analysis of how branded Suboxone film compared to generic buprenorphine naloxone tablets with regard to any measure of price or profitability and could not say whether patients would typically pay more for film as compared to generic tablets.

(Id. at 109:6–111:14, 126:6–130:7.) Indeed, at no point did Mr. Verscharen evaluate whether a medicine designed to combat opioid addiction would be suitable for a therapeutic substitution program. (Id. at 115:12–18.)

Moreover, even if Mr. Verscharen’s testimony could satisfy the “fit” element of Daubert, I cannot find that his methodology on this issue is sufficiently reliable. For witnesses relying solely or primarily on experience, as Mr. Verscharen does here, “then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for an opinion, and how that experience is reliably applied to the facts.” Floorgraphics, Inc. v. News Am. Mktg. In-Store Servs., Inc., 546 F. Supp. 2d 155, 165 (D.N.J. 2008) (citing Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1319 (9th Cir. 1995)). Mr. Verscharen, however, fails to connect his experience to his opinion. In fact, in his deposition, Mr. Verscharen revealed that his *actual* experiences belie his opinion that a therapeutic substitution for buprenorphine naloxone products would not work. He testified that he developed and worked in a Therapeutic Intervention Center for Thrift Drug, which was a department consisting of technicians and pharmacists that contact patients and physicians about programs or about products that they feel the physician and the patient should be aware of, and was designed to ensure that pharmacy stores were not taking the time “in doing some of the things that I wanted to communicate to physicians and patients.” (Def.’s Omnibus Mot., Ex. 43, Dep. of Robert Verscharen (“Verscharen Dep.”) 89:6–24.) More specifically, in lieu of an individual pharmacist engaging in the therapeutic substitution process described above, the center was staffed with approximately thirty technicians who would contact patients about potential cost savings in using a biosimilar drug and, if the patient approved it, the technicians would call the physician and get him/her to change the prescription. (Id. at 131:8–133:9.) This Therapeutic Intervention Center actually eliminated the precise time and cost factors

at the store level that made the Tricor therapeutic substitution unworkable—factors which Mr. Verscharen now opines claims would make therapeutic substitution unworkable here.

In short, Mr. Verscharen’s opinion is not an expert opinion, but rather a personal opinion based on one experience with a generic company trying a similar therapeutic program. He made no effort to specifically apply the factors at issue in that program to the unique circumstances of this case. Accordingly, I find that Mr. Verscharen can testify about the history of generic prescription drugs in the marketplace, with a focus on the rise of the substitution of AB-rated generic drugs for branded drugs from the perspective of the retail pharmacy level of distribution. (Verscharen Rep. ¶¶ 16–44.) He can also discuss the efficacy of automatic AB-rated generic substitution and the hurdles he specifically experienced in therapeutic substitution programs. (*Id.* ¶¶ 45–64.) He may not, however, make the speculative leap—as he does in his report—that similar problems would have likely rendered unsuccessful a therapeutic substitution program regarding Suboxone. Accordingly, I will grant this portion of Defendant’s Motion.

E. Opinions By Patricia Zettler

Defendant moves to exclude the report of Professor Patricia Zettler, who opines that: (1) Defendant’s involvement with the development of shared REMS with the generics directly delayed approval of that shared REMS; (2) had Defendant informed the FDA and the generics on January 12, 2012 that it did not intend to cooperate, the generics would have obtained approval of a waiver-granted BTOD SSRS, six months earlier than actual approval was obtained; (3) Defendant’s promotion of the Suboxone film as less prone to misuse, diversion, and pediatric exposure than the Suboxone tablet was false or misleading in violation of the Food, Drug & Cosmetic Act’s (“FDCA”) and FDA’s regulations because the claims were not supported by statistically significant data at the time; and (4) if she were an attorney counseling a drug sponsor client in the position of Defendant, she would have advised her client not to make such safety claims.

Defendant challenges Professor Zettler’s first and second opinions on two grounds.¹⁶ First, Defendant argues that Professor Zettler has no expertise regarding how long it takes to assemble an approvable REMS submission, nor does she report any expertise that would inform the assumptions underlying her timeline. Second, Defendant contends that Professor Zettler provides no methodology beyond “wishful thinking.”

1. Qualification

Professor Zettler graduated law school in 2009 and then worked in the Office of the Chief Counsel at the FDA for just under four years, after which she became a law school professor. Given that background, Defendant contends that her practical experience is limited. Citing to her deposition, Defendant notes that Professor Zettler has never advised a pharmaceutical manufacturer or client on proposed promotional messaging, never advised a pharmaceutical manufacturer or client regarding issues pertaining to a shared REMS program, and never served as an expert witness before. (Def.’s Omnibus Mot., Exs. 23–24, Dep. of Patricia Zettler (“Zettler Dep.”) 212:20–213:24.) Defendant also points out that Professor Zettler was never involved in any decision to grant a waiver from a shared REMS requirement and never worked on any shared REMS programs in which a waiver was requested. (*Id.* at 72:13–73:12.) Finally, although she reviewed and commented on REMS for the FDA, Defendant notes that she never drafted any REMS documents for the FDA and could not recall instances of dealing with a schedule by which manufacturers had to put together REMS documentation, (*Id.* at 288:10–294:10.) Defendant argues that Professor Zettler is not qualified to render an opinion on how long the shared REMS should or could have taken.

¹⁶ Defendant also challenges Zettler’s third and fourth opinions above, but raises them in the context of its “Motion to Exclude Plaintiffs’ Expert Opinions Asserting or Relying Upon Assertions that Alleged Reckitt Safety Messages Were ‘False,’ ‘Misleading,’ ‘Disparaging,’ ‘Fabricated,’ ‘Fraudulent,’ ‘Sham,’ or ‘Deceptive.’” I discuss these arguments *infra*.

Defendant improperly truncates Professor Zettler's experience. She is a lawyer, who served as associate chief counsel in the U.S. Food and Drug Administration's ("FDA") Office of the Chief Counsel, where she advised on various issues including drug safety, prescription drug advertising and promotion, clinical investigation oversight, drug labeling, expanded access to investigational drugs, over-the-counter drugs, dietary supplements, incentives for developing antibiotics, and advisory committees. (Def.'s Omnibus Mot., Ex. 1, Patricia Zettler Rep. ("Zettler Rep."), ¶ 1.) While at the FDA, REMS were one of her areas of specialization, and she "regularly met with agency personnel in the Center for Drug Evaluation and Research (CDER) involved with REMS, including personnel in CDER's Office of Regulatory Policy and Office of Surveillance and Epidemiology, provided advice on REMS for specific drugs and drug classes, including REMS with elements to assure safe use and single shared systems (SSRS), and reviewed and revised agency documents related to REMS." (*Id.* ¶ 9.) In addition, Professor Zettler specialized in prescription drug advertising and promotion, and she regularly provided advice on the FDA's policies for prescription drug advertising and promotion and whether drug companies' promotional activities violated relevant provisions of the FDCA and the FDA's implementing regulations. (*Id.* ¶ 10.)

After leaving the FDA, Professor Zettler served for two years as a Fellow and Lecturer at Stanford Law School where she conducted research on FDA regulation of drugs and devices and co-taught the law school's Food and Drug Law course, which covered, in part, the FDA's requirements for REMS and prescription drug advertising and promotion. (*Id.* ¶ 7.) She also worked as a professor at Georgia State University College of Law and, currently, at The Ohio State University College of Law, where she has continued to develop an expertise in FDA regulation, including the FDA's requirements for REMS and prescription drug advertising and promotion. (*Id.* ¶ 11–12.) From 2016 to 2017, Professor Zettler served as a consultant to the National Academies of Sciences, Engineering, and Medicine's Committee on Pain Management and Regulatory

Strategies to Address Prescription Opioid Abuse, where she provided advice on the FDA’s authority over and the regulatory history for prescription opioids, including issues associated with REMS and prescription drug advertising and promotion.¹⁷ (Id. ¶ 11.)

Given this extensive background, I have little trouble finding that Professor Zettler may render the opinions in her report. As repeatedly emphasized, “it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.” Kannankeril v Terminix Int’l, 128 F.3d 802, 809 (3d Cir. 1997).

2. Methodology

In January 2012, the FDA asked all generic manufacturers of buprenorphine medications to collaborate with Reckitt on a single, shared REMS (“SSRS”) by May 5, 2012. Given the contentious nature of the negotiations, the generic manufacturers submitted a proposed generics-only REMS, which the FDA rejected as inadequate. From that initial submission to approval, another 188 days passed due to additional deficiencies identified by the FDA. Professor Zettler opines that had Reckitt informed the FDA and the generics at the start of the REMS process, on January 12, 2012, that it did not intend to cooperate, the generics would have obtained approval of a waiver-granted BTOD SSRS six months earlier than actual approval was obtained.

¹⁷ During her deposition, Professor Zettler expanded on her FDA experience. (Zettler Dep. 38:15–40:19.) With respect specifically to shared REMS programs, Professor Zettler noted that she “provided legal advice on any issues that came up with those particular REMS . . . [and on] whatever legal issues might have come up for the agency” and specifically identified two REMS that she worked on with elements of shared safe use and single shared systems. (Id. at 60:3–61:12.) To the extent Defendant argues that Professor Zettler did not work on a waiver request while at the FDA, the DPPs accurately note that the SSRS waiver in this case was the first ever granted and it occurred just months before she left the FDA in 2013. (Id. at 273:6–274:11.) Nonetheless, based on her experience, she was able to discuss the waiver statute and its requirements. (Id. at 274:4–278:20, 284:6–286:22.)

Defendant contends that Professor Zettler's methodology in reaching this opinion is unreliable because the opinion rests on four assumptions: (1) the FDA would accept Reckitt's hypothetical refusal to negotiate rather than continuing to ask Reckitt to engage in negotiations; (2) after a Reckitt refusal to negotiate, it would take the FDA only twelve days to inform the generics that the FDA was willing to consider a waiver-granted SSRS, meaning that the generics could file their own REMS safety plan independent of Reckitt; (3) although the FDA had set a 120-day deadline for the submission of REMS documentation, the generics would have beaten the deadline by almost two months; and (4) instead of 188 days passing between the generics' initial submission and approval of their REMS, the time interval instead would have been only 165–175 days. Taking each assumption individually, Defendant attempts to debunk the opinion's validity and argues that Professor Zettler has no qualification or methodology by which to reach these various conclusions.

Defendant's challenge is an effort to establish facts before a jury rather than a proper Daubert attack on an expert's reliability. The Third Circuit has recognized that an expert may construct—as Professor Zettler does here—a reasonable offense-free world as a yardstick for measuring what, hypothetically, would have happened ‘but for’ the defendant's unlawful activities.” ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 292 (3d Cir. 2012) (quoting LePage's Inc. v. 3M, 324 F.3d 141, 165 (3d Cir. 2003)). When certain facts underlying the “but-for” world are in dispute “experts sometimes reach different conclusions based on competing versions of the facts. The emphasis . . . on ‘sufficient facts or data’ is not intended to authorize a trial court to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other.” Fed. R. Evid. 702, Advisory Committee's Notes (2000). In other words, Daubert “does not preclude testimony merely because it may be based on an assumption.” In re Dill Litig., 193 F.3d 613, 677 (3d Cir. 1999) amended 199 F.3d 158 (3d Cir. 2000). Rather, contentions that an expert's assumptions are

unfounded go to the weight, not the admissibility, of the testimony. Boucher v. U.S. Suzuki Motor Corp., 73 F.3d 18, 21 (2d Cir. 1996).

I find that Professor Zettler’s methodology meets the standard of reliability as she analyzed the real-world timeline of the SSRS-related activity, applied her knowledge of and experience with FDA policy and practice, and adjusted that timeline to reflect a world in which Defendant promptly refused to participate and was not involved in SSRS negotiations. Her report encompasses her review of Defendant’s internal planning documents, FDA communications, and generic actions and then constructs a detailed timeline of actions by Defendant that, in her opinion, delayed approval of the REMS. (Zettler Rep. ¶¶ 118–135.) Her report also describes, based on various communications and events, the timeline for the generics’ development of a single shared REMS had Defendant informed the FDA that it did not intend to participate in a single shared REMS on or about January 12, 2012. (Id. ¶¶ 136–43.) To the extent Defendant believes that Professor Zettler’s underlying assumptions are factually inaccurate or disproven by the evidence, it may raise those issues on cross-examination.

F. All Opinions By Deborah Jaskot

The final expert which Defendant individually challenges is Deborah Jaskot. Ms. Jaskot is a pharmaceutical industry consultant who has overseen and submitted hundreds of ANDAs to the FDA for review and approval. Based upon her thirty-plus-years’ experience in the pharmaceutical industry working on FDA regulatory matters, her knowledge of FDA regulations and practices, and her review of the evidence in this case, she offers two opinions. (Def.’s Omnibus Mot., Ex. 10, Deborah Jaskot Report (“Jaskot Rep.”) ¶ 18.) First, she avers that if the REMS and REMS-related labeling of the generics’ ANDAs were approved by the FDA between August 22, 2012 and September 1, 2012, there were no other regulatory hurdles or obstacles that would have prevented final approval of these two ANDAs during that same time frame. (Id.) Second, she opines that

Reckitt's September 25, 2012 Citizen Petition was deficient in multiple respects and the specific requests therein stood no reasonable chance of being granted. (*Id.* ¶ 19.) Defendant challenges both opinions.

1. Opinion on the "But-For" ANDA Approval Date

Defendant first contends that Ms. Jaskot has no foundation for her opinion that "but-for" Defendant's delay during the shared REMS, generic manufacturers Amneal and Actavis would have had their ANDAs for generic tablets approved between August 22, 2012 and September 1, 2012. Defendant reasons that a condition of approval of ANDAs is that the facilities that make both the finished product and its active ingredients comply with FDA regulatory requirements, namely the "Current Good Manufacturing Practices" ("cGMPs"). (*Id.* ¶ 44.) According to Defendant, however, both Actavis' supplier of active ingredients and Amneal's contract manufacturing facility were not cGMP-compliant as of September 1, 2012. Specifically, Defendant notes that (1) Actavis' ANDA relied upon active ingredients supplied by a facility operated by a contract manufacturer, Macfarlan Smith, which the FDA purportedly found had "objectionable conditions and practices" during an April 2012 inspection, and (2) Amneal's supplier of buprenorphine was not compliant with FDA regulations as of October 2012.

The DPPs respond that Ms. Jaskot's review of documents and application of her experience reveal a contrary conclusion: that there would have been earlier cGMP approval of both Actavis' active ingredient supplier and Amneal's contract manufacturing facility. The DPPs note that Ms. Jaskot details how cGMP inspections are conducted, how an FDA project manager ushers an ANDA through the FDA approval process, and why the Actavis supplier compliance status would have been found acceptable earlier had the rest of the ANDA been ready for approval between August 22 and September 1, 2012. (Def.'s Omnibus Mot. Ex. 15, Deborah Jaskot Rebuttal Report ("Jaskot Reb. Rep.") ¶¶ 59–63, 67–69.) In addition, the DPPs contend that Ms. Jaskot directly disputed that

there was a compliance impediment with Amneal's contract manufacturing facility that would have prevented approval of Amneal's ANDA before September 1, 2012. (*Id.* ¶¶ 39–40.)

Faced with a similar Daubert objection predicated on disputed evidence relied upon by the expert, the Third Circuit instructed:

An expert is . . . permitted to base his opinion on a particular version of disputed facts and the weight to be accorded to that opinion is for the jury. It is also, as the District Court observed, a proper subject for cross-examination. . . . [F]actual disputes are for the jury, and [plaintiff] was perfectly free to explore on cross-examination the reliance placed by [the expert] on the disputed facts and to argue to the jury that, if it rejected the underlying factual premises of his report, it should also reject [the] expert opinion . . .

Walker v. Gordon, 46 F. App'x 691 (3d Cir. 2002).

Here, the parties' disagreement is a dispute of fact not an issue of reliability under Daubert. Such disputes must be resolved by a fact-finder at trial, and, as such, I decline to exclude Ms. Jaskot's testimony on this ground.

2. Opinion on Reckitt's September 2012 Citizen Petition

Defendant also challenges Ms. Jaskot's report to the extent she offers the following opinion on Defendant's Citizen Petition:

It is furthermore my opinion that Reckitt Benckiser's September 25, 2012 Citizen Petition was deficient in several respects and the specific requests therein stood no reasonable chance of being granted because: (i) RB's request that generic applicants be required to engage in the same voluntary education practices as RB had no statutory support—the applicable statutes, regulations, and FDA practices only mandate that the labeling of generic drugs mimic the involuntary mandated labeling of the corresponding brand drug (with certain minor exceptions not applicable here); and (ii) RB itself admitted that the studies upon which it was relying for its requests that (1) FDA not approve ANDAs lacking unit-dose packaging and (2) FDA determine that Suboxone tablets were discontinued for reasons of safety, were incomplete, and thus, by definition, could not satisfy FDA's statutory requirements. Therefore, it is my professional opinion that each of the three specific requests in the Petition were factually and legally baseless, and that no reasonable petitioner could expect those requests

to be granted. Furthermore, if I had been in charge of overseeing the filing of Citizen Petitions at Reckitt Benckiser at the time, I would not have signed or agreed to file the September 25, 2012 Petition.

(Jaskot Rep. ¶ 19.)

Defendant contends that Ms. Jaskot's opinions are inadmissible on three grounds: (1) her opinion as to the purported "baselessness" of the Citizen Petition is an impermissible legal conclusion; (2) she admits to being unqualified to opine on the scientific basis of Defendant's Citizen Petition requests; and (3) her regulatory opinions fail to fit the undisputed facts of the case. As I agree with Defendant that this opinion is an impermissible legal conclusion, I will address only this issue.

District courts "must ensure that an expert does not testify as to the governing law of the case." Berkeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006). Expert witnesses are prohibited from rendering a legal opinion because "it would usurp the District Court's pivotal role in explaining the law to the jury." Id. (citing First Nat'l State Bank v. Reliance Elec. Co., 668 F.2d 725, 731 (3d Cir. 1981)). "[An] expert [is] not free to reach conclusions about the reasonableness of [a party's] beliefs when such an opinion necessarily would have required an interpretation of the relevant . . . law." In re Wellbutrin SR, Nos. 04-5525, 04-5898, 05-396, 2010 WL 8425189, at *3 (E.D. Pa. Mar. 31, 2010); see also QVC, Inc. v. MJC Am., Ltd., No. 08-3830, 2012 WL 13565, at *2 (E.D. Pa. Jan. 4, 2012) (noting that experts may not apply the resulting law to the facts of a case to draw a legal conclusion).

I addressed a similar challenge in King Drug Co. of Florence Inc. v. Cephalon, Inc., Nos. 06-1797, 06-1833, 06-2768, 2015 WL 6750899 (E.D. Pa. Nov. 5, 2015). In that antitrust case, the issues turned substantially on whether the litigation and settlement of a prior patent suit brought by two of the antitrust defendants was valid or whether that settlement was used to prevent later competition. Id. at *1. The defendants had sought to present expert testimony that various legal

arguments they made during the patent infringement lawsuit were “reasonable” and that a reasonable litigant in the defendants’ position could have realistically expected success on the merits. Id. at *15–16. In the face of a Daubert challenge by the plaintiff, the defendants contended that the experts were not presenting a legal opinion, but rather simply opining as to the customs and practices of the industry and the objective reasonableness of the parties’ patent positions. Id. at *17. The defendants further argued that the experts provided valuable insights for the jury on the factors considered by drug manufacturers when contemplating infringement settlements. Id.

I disagreed with the defendants and found that a key issue in the case was whether the prior patent litigation was objectively baseless, such that no reasonable litigant could realistically expect success on the merits, and that the baseless lawsuit furthered anticompetitive activity. Id. at *17. The proposed experts were attorneys evaluating the merits of a legal argument by applying facts to the law. Id. As such, I determined that the expert’s reasonableness opinions would “usurp the role of the jury and merely tell them which conclusion to reach as to an essential element.” Id. at *17–18.

Similarly, in In re Wellbutrin SR Antitrust Litig., supra, the plaintiff sought to introduce expert opinions in an antitrust case also involving a sham litigation claim. Id. at *2. The experts were attorneys who opined that the defendant could not have had a reasonable expectation of success in the litigation. Id. The court found that to the extent the experts would testify as to relevant background information, such as patent practice, patent application procedure, or other areas related to patent law that would be helpful for a trier of fact, the experts were admitted. Id. at *6. To the extent, however, that the experts testified as to governing legal standards and applied those standards to the relevant facts, the court deemed these opinions impermissible legal opinions. Id. at *7.

In response to those decisions, the DPPs rely on In re Flonase Antitrust Litig., 884 F. Supp. 2d 184, 200 (E.D. Pa. 2012). That case, like the one before me, involved alleged sham citizen

petitions. Id. at 188. The defendant offered an expert opinion that the petitions were “appropriate” and had “regulatory merit.” Id. at 195–96. Considering plaintiff’s Daubert challenge, the court allowed the expert to “explain that the petitions were ‘within the FDA’s jurisdiction’ of topics properly considered in the citizen petition process” or were “within the FDA’s purview.” Id. at 197. The court further noted that the expert’s testimony on the merits of the Citizen Petitions in the context of FDA regulatory policy and practice was relevant and helpful to the trier of fact. Id. at 198. However, the court concluded that the expert could not opine on the scientific merits of the citizen petitions and could merely offer opinions from an FDA regulatory and policy perspective. Id. at 199–200.

I find that Ms. Jaskot’s opinions are more akin to the opinions excluded in King Drug and Wellbutrin than the one admitted in Flonase. Ms. Jaskot’s opinion is not that Defendant’s Citizen Petition was outside the FDA’s jurisdiction of topics or that it did not satisfy the FDA’s rules for when such petitions may be filed. Rather, the opinion is that the Citizen Petition was “[f]actually and [l]egally [b]aseless.” (Jaskot Rep. p. 24.) Ms. Jaskot posits three reasons for her conclusion. First, as to Defendant’s request that the FDA not approve ANDAs that did not include a targeted pediatric exposure education program, Ms. Jaskot asserts that the studies relied upon by Defendant were insufficient and that the authority cited by Defendant did not legally support its request. (Id. ¶¶ 123–24.) Second, as to Defendant’s request that the FDA refrain from approving ANDAs that lack child-resistant unit-dose packaging, Ms. Jaskot opines that Defendant provided inadequate evidence to support this request. (Id. ¶¶ 125–26.) Third, as to Defendant’s request that the FDA not approve any ANDA for buprenorphine/naloxone tablets until it determined whether Defendant’s decision to discontinue the tablet was for safety reasons, Ms. Jaskot opines that the study relied upon by Defendant to pull its tablet from the market was inherently flawed and, therefore, Defendant did not have “a sound scientific basis to support the actions requested in the Petition.” (Id. at ¶¶ 127–

33.) Ms. Jaskot then concludes that “[Defendant]’s Petition was not supported by evidence. Based on my many years of experience in industry evaluating and responding to citizen petitions, it is my professional opinion that [Defendant] did not have sound scientific basis for each of the requests stated in the Petition, that the Petition was factually and legally baseless, and no reasonable petitioner could expect the Petition to be granted.” (*Id.* ¶ 133.)

Although Ms. Jaskot attempts to couch each of her statements in terms of whether the Citizen Petition conformed to the regulations governing the filing of citizen petitions, her opinion is, at its core, a pure legal conclusion as to whether the Citizen Petition had merit. This is not permissible. As one of the key issues in this case is whether Defendant’s Citizen Petition was factually and legally baseless and used entirely for anticompetitive purposes, I find that Ms. Jaskot’s opinion is a legal opinion that usurps the jury’s role in applying the law to the facts.

VI. DEFENDANT’S MOTION TO EXCLUDE PLAINTIFFS’ EXPERT OPINIONS ASSERTING OR RELYING UPON ASSERTIONS THAT ALLEGED RECKITT SAFETY MESSAGES WERE “FALSE,” “MISLEADING,” “DISPARAGING,” “FABRICATED,” “FRAUDULENT,” “SHAM,” OR “DECEPTIVE”

Defendant also seeks to preclude any of Plaintiffs’ experts from relying on the assumption that Defendant’s alleged safety claims were false, misleading, disparaging, fabricated, fraudulent, sham, or deceptive, including: (1) the DPPs’ economist experts’ assumption that Defendant’s safety claims were false in order to prove that Defendant’s alleged conduct was anticompetitive and resulted in measurable damages; and (2) Plaintiffs’ experts’ assumption that the allegedly false safety claims influenced the markets.

Proper consideration of this motion requires a more fulsome discussion of both the background of this issue and Defendant’s argument. As set forth above, Plaintiffs contend that as part of Defendant’s overall efforts to keep generic buprenorphine/naloxone tablets off the market and switch the market demand from tablets to branded film, Defendant developed a “safety story.”

According to Plaintiffs, Defendant repeatedly and without evidence claimed—both in marketing and promotion and in a Citizen Petition to the FDA—that tablets were more prone than film to a risk of pediatric exposure and to misuse, abuse, and diversion. Plaintiffs’ theory posits that via this safety story, Defendant attempted to sway physicians into prescribing only film and to impede FDA approval of generic tablets.

According to Defendant, however, the veracity of its “safety” claims are backed by substantial unrefuted evidence. In its current Motion, Defendant asserts that none of Plaintiffs’ expert opinions—aside from Professor Zettler’s inadmissible legal opinion—affirmatively state that film does not offer safety advantages relative to tablets. Absent such evidence, Defendant asserts that none of Plaintiffs’ experts can assume the falsity of Defendant’s alleged promotional statements regarding damages or impact on the market. Ultimately, Defendant seeks to preclude all of Plaintiffs’ experts from characterizing Defendant’s alleged marketing claims (including claims relating to safety, pediatric exposure, abuse, diversion, or misuse) as “false,” “misleading,” “disparaging,” “fabricated,” “fraudulent,” “unfounded,” “sham,” “baseless,” “deceptive,” or the like, and to strike any expert testimony that relies on such assumptions.

Defendant relies on five core assumptions: (a) Plaintiffs bear the burden of affirmatively proving the falsity of Defendant’s safety statements about Suboxone products; (b) no Plaintiff expert testifies or is qualified to testify that the statements were actually false; (c) Plaintiffs’ expert Patricia Zettler cannot testify that the statements were “false” under FDA standards; (d) falsity cannot be proven through lay testimony or evidence; and (e) therefore, no expert may rely on the presumed falsity of Defendant’s safety statements when rendering an opinion. I address each of these assumptions individually.

A. Whether Plaintiffs Must Affirmatively Prove that the Safety Statements Were Untrue

Defendant's first assumption turns on the definition of "false and misleading." In refuting Plaintiff's claims of false, disparaging, or fabricated safety claims, Defendant relies on a dictionary definition of "false" and "misleading" and contends that Plaintiffs must affirmatively prove that the safety statements at issue were untrue. Because Defendant argues that Plaintiffs have failed to meet this burden, Defendant presses that Plaintiffs' expert economists may not rely on such statements to prove antitrust impact or damages.

It is well established, however, that "[a]ntitrust analysis must always be attuned to the particular structure and circumstance of the industry at issue. Part of that attention to economic context is an awareness of the significance of regulation." Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411 (2004). Therefore, I must look to the FDA's marketing rules to determine whether Defendant's safety statements were indeed "false" or "misleading."

The FDA defines "marketing" as advertisements published in journals, magazines, and newspapers; advertisements broadcast through media such as television and radio; and advertisements in the form of physician-directed pitches by sales representatives, computer programs, and electronic media. Pennsylvania Emps. Ben. Trust Fund v. Zeneca Inc., 499 F.3d 239, 243 (3d Cir. 2007) (citing 21 C.F.R. § 202(l)(1)), vacated on other grounds, 556 U.S. 1101 (2009). "Although advertising may also serve as a mechanism to distribute safety information about a drug, its primary purpose—unlike labeling is not to promote safety but rather to promote market expansion." Id.

Under the relevant regulations

An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons, if it:

. . .

(ii) Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.

. . .

(iv) Contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated.

. . .

(v) Presents information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does.

21 C.F.R. § 202.1(e)(6).

Thus, the standard for whether the statements at issue here are “false, lacking in fair balance, or otherwise misleading” does not turn, as Defendant urges, on whether the statements are untrue, but rather on whether Defendant had substantial evidence or substantial clinical experience to support those statements. “Substantial evidence” is defined as “adequate and well-controlled investigations, including clinical investigations . . . by experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug involved, on the basis of which it can fairly and responsibly be concluded by such experts that the drug is safe and effective for such uses.”

21 C.F.R. § 202.1(e)(4)(ii)(b). “Substantial clinical experience” means “substantial clinical experience adequately documented in medical literature or by other data . . . on the basis of which it can be fairly and responsibly be concluded by qualified experts that the drug is safe and effective for such uses.” *Id.* at § 202.1(e)(4)(ii)(c). Indeed, FDA officials have explained:

Promotional labeling or advertising is considered false or misleading if it contains claims that are not supported by substantial evidence. This includes, for example, claims about product uses (indications), dosing, and advantages over other products or interventions. Thus, comparative claims of effectiveness or safety in promotional labeling

and advertising generally must be supported by substantial evidence from adequate and well-controlled trials that demonstrate that the drug will have the claimed effect (for example, superiority over another treatment).

To be considered “substantial evidence” of effectiveness, the trials would generally have to been designed to provide a fair and valid head-to-head comparison of the treatments in question (for example, the doses of compared products and treatment duration should be clinically comparable)

(Pls.’ Resp. to Def.’s Safety Mot., Ex. 23, Joseph P. Griffin, et al., “Regulatory Requirements of the Food and Drug Administration Would Preclude Product Claims based on Observational Research,” 31 Health Affairs 2188, 2190 (2012).)

Defendant attempts to avoid these regulations by positing two arguments. First, it contends the FDA advertising regulations have little bearing on the issue here because violations of the FDCA or its related regulations, even if proven, “do nothing to illuminate whether an antitrust violation occurred.” (Def.’s Mot. to Preclude Expert Reliance on Allegedly False Safety Messages (“Def.’s Safety Mot.”) 12.) Citing to the Third Circuit’s decision in Philadelphia Taxi Assoc., Inc. v. Uber Techs., Inc., 886 F.3d 332 (3d Cir.), cert denied, 139 S. Ct. 211 (2018), Defendant contends that even if a defendant was “able to cut costs by allegedly violating . . . regulations, [the plaintiffs] cannot use the antitrust law to hold [the defendant] liable for these violations absent proof of anticompetitive conduct.” Id. at 340.

Defendant’s citation, however, avoids the very next portion of the sentence in Philadelphia Taxi, which states that “[e]ven unlawful conduct is ‘of no concern to the antitrust laws’ *unless it produces an anticompetitive effect.*” Id. (quotations omitted) (emphasis added); see also In re Thalomid & Revlimid Antitrust Litig., No. 14-6997, 2015 WL 958927, at *16 (D.N.J. Oct. 29, 2015) (allowing antitrust plaintiff to prove violation of FDA regulations as part of an overall anticompetitive scheme). As I noted previously, “a plaintiff can allege a series of actions that when

taken together make out antitrust liability even though some of the individual actions, when viewed independently, are not all actionable.” In re Suboxone Antitrust Litig., 13-2445, 2017 WL 36371, at *8 (E.D. Pa. Jan. 4, 2018) (citing cases); see also In re Gabapentin Patent Litig., 649 F. Supp. 2d 340, 359 (D.N.J. 2009) (“If a plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability.”).

The allegation here is multi-layered: Defendant’s repeated and willful violations of FDA advertising regulations in the form of unsubstantiated or “false” warnings about the comparative safety benefits between film and tablets—combined with the increase in the price of tablets and decrease in the price of film, the introduction of Suboxone film onto the market, the removal of Suboxone tablets from the market several months prior to generic approval, delay in the shared REMS, and an improper citizen petition—all contributed to a pattern of anticompetitive conduct resulting in an anticompetitive effect. To that end, Plaintiffs need not affirmatively prove that Defendant’s marketing statements were “false” or “misleading” in the sense of being untrue. Rather, they need only prove that, at the time those statements were made, Defendant did not have substantial evidence or statistically significant data from head-to-head clinical trials.

Defendant’s second effort to avoid the regulatory definition given to the terms “false” and “misleading” cites the Merriam-Webster Dictionary definition of “false” and “misleading” and asserts that these terms—as well as the terms “fabricated,” “fraudulent,” “sham,” or “deceptive”—have well-understood colloquial meanings that signify dishonesty and deception and suggest that Defendant’s safety claims were wrong. Defendants posits that a juror will not fully understand in the context of the case that the words “false” or “misleading,” as used by Plaintiffs’ experts, simply mean that “at the time the claims were made, they were not supported by statistically significant data from head-to-head clinical trials.”

Defendant's concerns are nothing more than a fear that the jurors will not comprehend its theory of the case. To the extent that a witness testifies that certain marketing statements were false, misleading, or otherwise deceptive, counsel may use opening statements, closing statements, direct examination, or cross-examination to clarify the meaning of those terms. If a witness suggests that the marketing statements had the colloquial definition of false, counsel may use cross-examination to underscore that the witness has no such actual knowledge. Finally, Defendant will be free to request appropriate jury instructions on this issue. The mere possibility of confusion does not constitute grounds for disregarding the clear statutory and regulatory meaning of "false and misleading."

In short, to establish that Defendant's marketing and promotional statements comparing the safety of film and tablets were deceptive—as part of Defendant's overall anticompetitive scheme to prevent the intrusion of generic tablets on the market—Plaintiffs need only prove that the promotional statements were "false and misleading" as defined by the FDA. Under the FDA regulations, Defendant was not permitted to make statements about or offer comparisons between its drug and other drugs unless it had, at the time the statements were made, substantial evidence or substantial clinical experience to support those statements. To the extent Defendant did not have such evidence at the time it made those statements, Plaintiffs may properly rely on Defendant's actions—as part of an overall antitrust scheme—to establish an anticompetitive effect.

B. Whether Plaintiffs Have Expert Testimony to Support Their Claim that the Statements Were "False and Misleading"

Defendant's second assumption asserts that none of Plaintiffs' experts can opine that film does not offer safety advantages relative to tablets. Defendant reasons that only two of Plaintiffs' experts—Drs. Westreich and Jewell—claim to possess expertise allowing them to analyze the scientific and epidemiological evidence relating to the safety of Suboxone film and Suboxone

tablets. Both witnesses, however, clearly acknowledge that they will not express an opinion as to whether or not film would pose fewer safety risks to public health as compared to Suboxone tablets and that they did not make affirmative findings regarding whether film is better, worse, or the same as compared to tablets with regard to any metric. (Westreich Dep. 189–90; Jewell Dep. 22–25.) Rather, these witnesses conclude that there is simply not enough evidence to determine one way or another whether film offers diminished susceptibility to risks of pediatric exposure, or use, misuse and diversion. According to Defendant, such testimony is insufficient to establish that Defendant’s statements were “false” or “misleading.”

Plaintiffs, however, do not purport to offer an expert to directly rebut Defendant’s statements that film poses fewer safety risks than tablets. Rather, Plaintiffs’ experts seek to testify that Defendant’s safety claims were not grounded in fact and science and were not supported by substantial evidence or substantial clinical studies. To that end, Plaintiffs proffer the testimony of Nicholas Jewell who (a) considers, from a statistical perspective, the data, analysis, and conclusions regarding the comparative safety of the film formulation of Suboxone versus the tablet formulation of Suboxone as set forth in two articles upon which Defendant relied, RADARS I and RADARS II; and (b) comments on the reliability, from a statistical perspective, of certain analyses purporting to compare the persistency and relapse rates of patients taking the formulation of Suboxone or the tablet formulation. (Jewell Rep. ¶ 9.) Based on multiple factors detailed throughout his report, Dr. Jewell opines that the conclusions set forth in the RADARS I and RADARS II articles were not reliable and, therefore, any claims by Defendant that tablets were less safe than film were “without substance statistically.” (Id. ¶¶ 10–15.)

Plaintiffs also offer Dr. Laurence Westreich who connects the “false and misleading” statements to the alleged anticompetitive impact. Dr. Westreich opines that “[b]ased on [his] experience training other doctors, working in hospitals and clinics, serving on panels and medical

associations, and interacting with other doctors,” he, as the “average, reasonable” physician, would be impacted and influenced by Reckitt’s claims about the tablets’ dangers, would have maintained an anti-tablet bias after generic tablets became available, and would have factored information about impending tablet withdrawal into treatment decisions. (Westreich Rep. ¶¶ 235–70.) In addition, Dr. Westreich offers an assessment, based on his experience in peer review, of whether the circumstances under which certain of Reckitt’s studies were prepared violated well-established safeguards on independent, accurate, and reliable studies. (See, e.g., Westreich Rep. ¶ 103 (“Medical research that is solely funded by pharmaceutical companies often draws questions of reliability. Studies that are entirely paid for by pharmaceutical companies tend to have results that favor the industry.”); ¶ 109 (discussing different types of bias that can occur in studies); ¶ 147 (“From the early planning stages, Reckitt had substantial involvement in creating the objectives, design, execution, and ultimate wording of the pediatric exposure analysis.”); ¶ 155 (“documents extrinsic to the paper also show that it was finalized under extraordinary time pressures, which may also have contributed to data inaccuracies.”); ¶ 189 (“as with the Pediatric Exposure Analysis, Reckitt Benckiser had substantial input into the design of the Lavonas Abuse and Diversion study.”).) None of these statements/opinions speak to false safety claims.

In short, neither Dr. Jewell nor Dr. Westreich opines, from a scientific standpoint, that Defendant’s safety claims were wrong. They need not do so under FDA standards. Rather, these experts provide an opinion that the underlying studies on which Defendant based its statements did not constitute “substantial evidence”—*i.e.*, they were not “adequate and well-controlled investigations, including clinical investigations . . . by experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug involved, on the basis of which it can fairly and responsibly be concluded by such experts that the drug is safe and effective for such uses.”

21 C.F.R. § 202.1(e)(4)(ii)(b). In turn, I find that the opinions of these experts provide an adequate foundation for the assertion that Defendant's safety messages were false and misleading.

C. Whether Professor Zettler May Opine that Defendant's Statements Were "False" or "Misleading"

Plaintiffs also offer Professor Patricia Zettler who opines in part that (a) Reckitt's promotion of the Suboxone film as less prone to misuse, diversion, and pediatric exposure than the Suboxone tablet was false or misleading in violation of the FDCA and FDA's regulations because the claims were not supported by statistically significant data at the time; and (b) if she were an attorney counseling a drug sponsor client in the position of Reckitt, she would have advised her client not to make such safety claims. Specifically, she states:

Reckitt's promotion of the Suboxone Film product as less prone to misuse, diversion, and pediatric exposures than the Suboxone Tablet product was false or misleading in violation of the FDCA and FDA's regulations, and inconsistent with FDA policies, because, at the time the claims were made, they were not supported by statistically significant data from head-to-head clinical trials adequately designed to compare the two products or equivalently robust data.

(Zettler Rep. ¶ 19(c).)

Defendant posits four challenges to Professor Zettler's opinion. First, it again challenges her qualifications. Second, it asserts that her opinions constitute improper legal conclusions. Third, it argues that her legal opinions are irrelevant to antitrust liability. Finally, it claims that Professor Zettler's legal opinion rests on a botched legal analysis.

1. Qualification

Defendant first alleges that Professor Zettler is not qualified to assess whether any safety claim is either proven or substantiated, as she is a lawyer without a professional background in epidemiology, statistics, or medicine. Professor Zettler, however, makes no attempt to look at scientific evidence or scientifically study whether film has any safety benefits as opposed to tablet

products. Accordingly, I need not address her qualifications from that perspective. As set forth in detail supra, I find Professor Zettler qualified under Daubert to render the opinions set forth in her report.

2. Improper Legal Conclusion

Defendant next argues that Professor Zettler's opinion that alleged safety claims did not comply with the FDCA and FDA regulations is an improper legal conclusion. Defendant urges that because Professor Zettler explores the legal question of whether Defendant's marketing claims applied to her interpretation of the governing regulations and statutes, it is pure exercise in statutory interpretation and not appropriate for expert review.

As explained in detail above, expert witnesses are prohibited from rendering a legal opinion because "it would usurp the District Court's pivotal role in explaining the law to the jury." Berkeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006). Nonetheless, "expert testimony that implicates or touches on legal issues is not *per se* inadmissible." Comcast Cable Commc's, LLC v. Sprint Commc's Co., 203 F. Supp. 3d 499, 546 (E.D. Pa. 2016). "Courts recognize that where expert testimony concerns the interpretation or explanation of complex areas of law difficult for a layperson to understand, expert testimony may be proper." In re Wellbutrin SR Antitrust Litig., Nos. 04-5525, 04-5898, 05-396, 2010 WL 8425189, at *3 (E.D. Pa. Mar. 31, 2010) (citing cases). As observed by the court in In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164 (S.D.N.Y. 2009):

A lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the pharmaceutical industry. [The expert's] assessment of the reasonableness of Merck's conduct in light of her experience and her understanding of FDA regulations will be helpful to the jury. An expert may offer testimony embracing an ultimate issue of fact that the jury will decide. Fed. R. Evid. 704(a). Cross-examination and competing expert testimony by Merck's regulatory experts will ensure that the jury carefully weighs her testimony.

Id. at 190–91.

Numerous courts have found that “the testimony of regulatory experts on the reasonableness of a pharmaceutical company’s conduct in light of the complex nature of the FDA framework is helpful to a jury.” In re Mirena IUD Prods. Liab. Litig., 169 F. Supp. 3d 396, 478–79 (S.D.N.Y. 2016) (citing Wells v. Allergan, Inc., No. 12-973, 2013 WL 7208221, at *1 (W.D. Okla. Feb. 4, 2013) (finding expert testimony about FDA regulations would not “usurp” the role of the trial judge); In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., No. 09-2100, 2011 WL 6302287, at *25 (S.D. Ill. Dec. 16, 2011) (discussing FDA regulations and finding that “[t]o the extent [the expert] does offer legal conclusions, the Court finds that [the expert’s] testimony is permissible because of the complex nature of the process and procedures and the jury needs assistance understanding it. [The expert’s] testimony will assist the trier of fact in understanding the federal regulations, and the jury will be instructed that that the Court, not [the expert] nor any other witness, will instruct the jury on the law in this case.”); In re Fosamax, 645 F. Supp. 2d at 191 (denying motion to preclude expert from “testifying about general FDA regulatory requirements and procedures or offering an opinion as to [the pharmaceutical company’s] compliance therewith”). In particular, courts have repeatedly allowed FDA regulatory experts to testify regarding regulatory requirements under the FDA. See, e.g., Wolfe v. McNeil-PPC, Inc., 881 F. Supp. 2d 650, 659–60 (E.D. Pa. 2012) (experts permitted to testify that defendants withheld information from FDA and failed to conduct a proper safety analysis); Bartoli v. Novartis Pharm. Corp., No. 13-724, 2014 WL 1515870, at *7 (M.D. Pa. Apr. 17, 2014) (finding that expert could opine on the reasonableness of defendant’s conduct in its interactions with the FDA and compliance with FDA regulations, including defendant’s interactions with FDA with respect to labels and warnings); Pfizer v. Teva Pharms. USA, Inc., 461 F. Supp. 2d 271, 278–79 (D.N.J. 2006) (finding

admissible expert testimony regarding FDA regulation of labeling, advertising, and promotion of prescription drugs, and to what extent the pharmaceutical company complied with those requirements).

Here, the key issue in this case is not whether Defendant violated FDA regulations regarding its marketing of film and its safety statements regarding tablets.¹⁸ Rather, it is whether Defendant made unsupported safety claims regarding Suboxone tablets in an effort to divert the market away from tablet prescriptions and further its alleged anticompetitive scheme. To that end, Professor Zettler engages in an extensive discussion of the regulations regarding advertising and promotion in the prescription drug industry. Specifically, she states:

- Under FDA regulations, a drug sponsor generally cannot make claims regarding the safety and effectiveness of its drug product unless and until those claims are supported by sound scientific evidence at the time they are made, regardless of whether such claims are made in writing or orally. (*Id.* ¶ 51.)
- The requirement to comply with FDA marketing regulations and policies is well known in the pharmaceutical industry. Promotional materials provided to healthcare professionals on behalf of a company should make claims about a product only when substantiated (*Id.* ¶ 144.)
- Defendant understood that FDA and FDCA promotional materials had to have statistically significant data supporting the claims made therein in order to avoid being “false, lacking in fair balance, or otherwise misleading.” (*Id.* ¶¶ 145–51.)

¹⁸ Defendant cites to several cases for the proposition that the meaning of federal regulations is not a question of fact on which experts may opine, but rather a question of law to be resolved by the court. These cases are distinguishable. In Bammerline v. Navister International Transportation Corp., 30 F.3d 898 (7th Cir. 1994), for example, a driver brought an action against a truck manufacturer for injuries sustained in an accident, alleging that the manufacturer designed the seat belt assembly improperly. *Id.* at 900. Given that the ultimate issue in the case involved whether the seat belt assembly was defective, the court found that an expert’s testimony that the seat belt assembly did not comply with Federal Motor Vehicle Safety Standards impermissibly usurped the role of the jury. *Id.* Similarly, Gordon v. New England Central Railroad, Inc., No. 17-154, 2019 4068639 (D. Vt. Aug. 28, 2019) involved a negligence claim against a railroad for failure to appropriately maintain track facilities. The court found that an expert report which was to “determine the standard of care” under federal regulations was an improper legal conclusion because “standard of care” is a legal decision within the province of the court. *Id.* at *3. It further found that expert’s opinion that the violation of federal regulations caused the collapse of the embankment was an ultimate conclusion exclusively within the province of the jury. *Id.*

- From 2009 to August 2010, Defendant actively promoted Suboxone Film as safer than Suboxone tablets because it had lower risks of abuse, diversion, and misuse and because it had a lower risk of unintended pediatric exposure. (*Id.* ¶¶ 152–54.)
- At the time Defendant was issuing those statements, there was insufficient data to support the accuracy of claims that the Film product was less prone to misuse, diversion, and pediatric exposures than the tablet product was. FDA officials on multiple occasions concluded that the existing evidence did not support those assertions, and Defendant’s own documents and testimony show that the company was not aware of sufficient scientific evidence to support its claims that Film was safer than tablets. (*Id.* ¶¶ 155–60.)

Such testimony may assist a jury not only in understanding the federal regulations and what they require, but also how Defendant’s own testimony and admissions reveals that its communications did not comply with FDA and FDCA standards for prescription drug promotional materials.

However, the next two paragraphs of Professor Zettler’s report cross the line into an inadmissible legal opinion when she reaches her final conclusions that: (1) Defendant’s claims that film was less prone to misuse, diversion, and pediatric exposures than tablets were false or misleading under the FDCA and FDA regulations, in that the claims were not substantiated by sufficient scientific evidence at the time they were made, and (2) had Defendant been her client, she would have advised it that it should not make claims that film was safer than tablets because such claims would violate FDA requirements in the absence of head-to-head clinical trials adequately designed to compare the products or equivalently robust scientific evidence. (*Id.* ¶¶ 161–62.) Such conclusions are for the jury to reach upon application of the law to the facts. Therefore, to the extent Professor Zettler seeks to offer these ultimate opinions, her testimony will be excluded.

3. Relevance

Defendant’s third challenge to Professor Zettler’s opinion contends that her opinions are irrelevant. It posits that Plaintiffs cannot bring a private cause of action under the FDCA, and that violations of the FDCA or its regulations, even if proven, do nothing to illuminate whether an

antitrust violation has occurred. Thus, Defendant concludes that testimony about alleged FDCA violations tells us nothing about whether such conduct had an anticompetitive effect.

This argument represents yet another attempt by Defendant to sever Plaintiffs’ theory into several individual causes of action. As I have previously noted, false or misleading disparagement of another company’s product “can give rise to antitrust liability, especially when it is combined with other anticompetitive acts.” In re Suboxone Antitrust Liab., 64 F. Supp. 3d 665, 682 (3d Cir. 2014) (quotations and citations omitted). I further remarked that “[t]he threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film.” Id.; see also Int’l Travel Arrangers, Inc. v. Western Airlines, Inc., 623 F.2d 1255, 1268 (8th Cir. 1980) (holding that alleged monopolist’s false, misleading, and deceptive advertising against another company for the purpose of preventing any effective competition was an unreasonable restraint of trade). Thus, although Plaintiffs cannot use antitrust law to hold Defendant liable for stand-alone violations of administrative regulations or unlawful conduct, those violations are relevant to Plaintiffs’ proof of an overarching scheme that had an anticompetitive effect. I decline to exclude Professor Zettler’s report on this ground.

4. Reliability

Defendant’s final challenge to Professor Zettler’s analysis contends that it rests upon a “botched legal analysis.” (Def.’s Safety Mot. 13.) In support of this position, Defendant sets forth three arguments.

First, Defendant contends that Professor Zettler’s analysis is untethered to the text of the FDCA because she relies on a provision of the FDCA that a drug is misbranded if “[i]ts labeling is false or misleading.” 21 U.S.C. § 352(a). But, according to Defendant, the definition of “labeling” is limited to “written, printed, and graphic material,” 21 U.S.C. § 321(m), and almost all of the

alleged communications Professor Zettler deems “false and misleading” are oral discussions or internal memorandum.

Professor Zettler’s opinion, however, is not limited to “labeling,” but rather focuses on “prescription drug advertising and promotion.” (Zettler Rep. ¶ 145.) As noted above, the FDA defines marketing as advertisements published in journals, magazines, and newspapers; advertisements broadcast through media such as television and radio; *and advertisements in the form of physician-directed pitches by sales representatives, computer programs, and electronic media.* Pennsylvania Emps. Ben. Trust Fund v. Zeneca Inc., 499 F.3d 239, 243 (3d Cir. 2007) (emphasis added) (citing 21 C.F.R. § 202(l)(1)); see also In re Schering-Plough Corp. Intron/Temodar Consumer Class Action, No. 06-5774, 2009 WL 2043604, at *2 (D.N.J. July 10, 2009) (“In addition to regulating the labeling of prescription drugs, the FDA is also empowered under the FDCA to regulate prescription drug advertising and marketing, *including marketing directed at physicians and the medical community at large.*”) (emphasis added); IMS Health, Inc. v. Ayotte, 490 F. Supp. 2d 163, 168 (D.N.H. 2007) (noting that the FDA is “authorized to take enforcement action against companies that use false and misleading advertising materials. . . . This regulatory authority also extends to oral misrepresentations by sales representatives.”). Thus, I find no merit to Defendant’s first argument.

Second, Defendant contends that courts construing the FDCA’s misbranding provisions in light of the protections of the First Amendment have held that an accusation of misbranding cannot be established absent proof that a claim was untrue. The cases cited by Defendant in support of this proposition are distinguishable, as they involve criminal prosecution of a drug company for violations of the branding regulations. See United States v. Caronia, 703 F.3d 149, 162 (2d Cir. 2012) (finding that FDCA’s misbranding provisions do not criminalize the simple promotion of a drug’s off-label use by pharmaceutical manufacturers and their representatives “because such a

construction—and a conviction obtained under the government’s application of the FDCA—would run afoul of the First Amendment.”); Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F. Supp. 3d 196, 224 (S.D.N.Y. 2015) (holding that under Caronia, the FDA may not bring a misbranding action against a manufacturer based on truthful promotional speech alone). This case, by contrast, is not a misbranding action brought by a governmental entity, but rather an antitrust action alleging that Defendant’s “false and misleading” promotion—as defined by the applicable regulations—was part of a broader antitrust scheme to preclude generic competition. Defendant offers no authority for the proposition that such an action is violative of the First Amendment.

Finally, Defendant contends that Professor Zettler relies on a regulation relating to “advertisement[s] for a prescription drug,” which states that comparative claims should be demonstrated “by substantial evidence or substantial clinical experience.” According to Defendant, however, Professor Zettler does not analyze any advertisements. Moreover, Defendant asserts that no authority requires head-to-head clinical trials in the promotional advertising sphere, and that FDA guidance provides that promotional claims are subject only to the lesser “competent and reliable information” standard.

These arguments are not a basis for exclusion of Professor Zettler’s testimony—indeed, they highlight its necessity. FDA regulations and their application are confusing, such that a jury cannot be expected to understand them without expert assistance. Flaws in Professor Zettler’s discussion of FDA regulatory standards are easily and more appropriately addressed on cross-examination or through Defendant’s own rebuttal experts.

5. Conclusion as to Professor Zettler

In sum, although Professor Zettler cannot offer an opinion as to whether Defendant’s promotional statements were “false and misleading,” she may provide expert testimony regarding

the requisite standards under the regulations. Additionally, she may discuss, based on her review of relevant documents, what type of support Defendant had for its safety claims.

D. Whether Falsity May Be Proven Through Lay Testimony or Evidence

Defendant's next assumption rests on the notion that Plaintiffs cannot "use non-expert testimony provide a foundation for their experts' assumptions on the supposed falsity of Reckitt's alleged safety claims." (Def.'s Safety Mot. 17.) Defendant goes on to cite numerous cases for the proposition that courts have required expert testimony in pharmaceutical product liability cases on issues of causation. They assert that comparative pharmaceutical safety—such as comparisons between Suboxone tablet and Suboxone film—is beyond the experience and understanding of lay jurors. Yet, according to Defendant, Plaintiffs have no expert testimony to this issue. Moreover, Defendant challenges Plaintiffs' reliance on an FDA "General Advice letter" from 2010 stating that the FDA did not agree that Reckitt had proven that film's packaging "provides meaningful incremental protection against pediatric exposure." (Def.'s Safety Mot., Ex. 47.)

Defendant's analysis is flawed for two reasons. First, and as repeatedly set forth above, in order to establish that Defendant's safety claims were false and misleading, Plaintiffs need not affirmatively prove that tablets were as safe or safer than film. Rather, under the FDA regulations, they need only establish that Defendant lacked a reliable scientific basis on which to make their safety claims. To that end, Plaintiffs have proffered expert witness testimony from Professor Jewell and Dr. Westreich, both of whom opine as to the reliability of the studies on which Defendant based its safety claims. Moreover, Plaintiffs offer Professor Zettler to describe FDA marketing regulations and discuss what constitutes substantial evidence to support a comparative pharmaceutical claim. Plaintiffs need not offer any expert testimony to prove that film was not, in fact, safer than tablets.

Second, Plaintiffs have put forth documentary evidence that Defendant lacked a scientific basis for its claim, including (1) the FDA's June 2009 internal memorandum that Defendant's film

NDA “[did] not provide evidence to compare the safety profile of the Suboxone strip to the Suboxone tablet”; (2) the FDA’s 2010 letter stating that the FDA did not agree that Defendant had proven that film’s packaging provided “meaningful incremental protection against pediatric exposure” because Defendant provided “no data” to support this claim;¹⁹ and (3) the FDA’s August 2010 medical review stating that although Defendant “has implied that [Film] may represent an advantage over the current tablet products with respect to diversion . . . there is no basis for comparison, [and] there does not appear to be any reason to conclude that this formulation rendered the study drug particularly resistant to diversion.” (Pls.’ Resp. to Safety Mot., Ex. 4 ¶ 144; Ex. 1 ¶ 96; Ex. 12 ¶ 156.) To the extent Defendant can rebut this evidence at trial, it is free to do so, and the jury can choose which story to credit.

Simply put, such “non-expert” evidence provides a foundation on which Plaintiffs can claim that, under the FDA regulations, Defendant’s safety claims were “false and misleading.”

E. Whether Plaintiffs’ Experts on Antitrust Impact and Damages May Rely on Assertions that Defendant’s Safety Messages Were False or Misleading

As a culmination of its motion, Defendant contends that Plaintiffs’ experts cannot rely on the unproven assumption that film safety claims are false. According to Defendant, Plaintiffs’ causation and damages experts purport to rely on a conclusion that has not been substantiated by any Plaintiff expert: that film does not provide safety benefits with respect to pediatric exposure, abuse, or diversion. Arguing that it is an abuse of discretion to admit expert testimony which is

¹⁹ Defendant asserts numerous challenges to this letter, arguing that (a) it does not state that the safety claims were false; (2) to the extent it can be read to state that film did not possess any safety benefits, “the letter would be expressing an inadmissible opinion with no foundation”; and (3) the passages relied upon by Plaintiffs are inadmissible hearsay. These arguments are not appropriate for resolution in this Daubert motion.

based on assumptions lacking any factual foundation in the record,²⁰ Defendant requests that I preclude all of Plaintiffs' experts from characterizing Defendant's alleged marketing claims as "false," "misleading," "disparaging," "fabricated," "fraudulent," "unfounded," "sham," "deceptive," or the like, and strike all such testimony contained within the reports of Plaintiffs' experts Professor Zettler, Dr. Berndt, Dr. Conti, Dr. Emch, Ms. Jaskot, Dr. Lamb, Ms. Tso, and Dr. Verscharen.

Defendant's request, however, asks me to rule on an issue of fact, *i.e.*, whether Defendant had substantial evidence to support its safety claims at the time they were made. Neither Daubert motions nor summary judgment motions are proper vehicles for such a request. Rather, "[a] party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination." Stecyk v. Bell Helicopter Textron, Inc., 295 F.3d 408, 414 (3d Cir. 2002). Thus, to the extent that Plaintiffs can prove at trial that Defendant's safety claims were "false and misleading" as defined in the FDA and FDCA regulations, Plaintiffs' causation and damages experts may analyze these claims, in conjunction with the remainder of Defendant's challenged conduct, to opine on the ultimate effect on the market and resulting damages.

VII. CONCLUSION

I will grant the Phase I Daubert Motions in part and deny them in part as detailed in this Opinion. An appropriate Order follows.

²⁰ Defendants cite two cases for this proposition, neither of which are applicable here. See Meadows v. Anchor Longwall and Rebuild, 306 F. App'x 781, 790 (3d Cir. 2009) (excluding expert where testimony did not fit with the otherwise uncontroverted evidence before the court); Brugler v. Unum Grp., No. 15-1031, 2019 WL 4452226, at *15 (M.D. Pa. Sept. 17, 2019) (excluding expert testimony where it was based on mere assumptions without any factual founding, thus rendering testimony unreliable).